U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

GRANT APPLICATION - PHASE II

RECEIPT DATES

NATIONAL INSTITUTES OF HEALTH
April 1, August 1, and December 1
(SBIR and STTR)

CENTERS FOR DISEASE CONTROL AND PREVENTION
April 1 and December 1
(SBIR)

FOOD AND DRUG ADMINISTRATION
April 1, August 1, and December 1
(SBIR)

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SBIR AND STTR REMINDER SHEETS (PDF)
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NIH SBIR/STTR INTERNET GUIDE (HTML)

ESTIMATED PUBLIC REPORTING BURDEN

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless such collection displays a valid OMB control number. The PHS estimates that it will take approximately 40 hours to complete this application for a regular research project grant. This estimate does not include time for development of the scientific plan. Items such as Human Subjects and Vertebrate Animals are cleared and accounted for separately. Therefore, these items are also not part of the time estimate. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001). *Do not send applications to this address*.

If you have comments or concerns regarding the status of your individual submission of your application, write directly to:

Ms. Jo Anne Goodnight
SBIR/STTR Program Coordinator
6705 Rockledge Drive
Rockledge I, Room 3534
Bethesda, MD 20892
Phone: 301-435-2688
Fax: 301-480-0146
Email: jg128w@nih.gov

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMALL BUSINESS INNOVATION RESEARCH (SBIR)
AND
SMALL BUSINESS TECHNOLOGY TRANSFER RESEARCH (STTR)
PHASE II GRANT APPLICATIONS

READ THE FOLLOWING IMPORTANT INFORMATION AND REMINDERS IN THIS SOLICITATION

CHANGES

RECENT CHANGES IN SBIR LEGISLATION

The SBIR Program has been reauthorized (P.L. 106-554) through 2008. The authorizing SBIR legislation requires two significant programmatic changes:

- ***Commercialization Plan.*** All Phase II applications must include a succinct Commercialization Plan. For more detailed instructions, see Item j of the Research Plan: Commercialization Plan (formerly Product Development Plan [PDP]).

- ***Phase II Data Collection Requirement.*** Each Phase II applicant is required to provide information for the SBA Tech-Net Database System (http://technet.sba.gov). *Questions about this requirement may be submitted to SBA directly through the Tech-Net URL*. Each Phase II awardee is required to update the appropriate information on the award in the Tech-Net database upon completion of the last deliverable (e.g., Final Report, Financial Status Report, Invention Report) under the funding agreement and is requested to voluntarily update the information in the Tech-Net database annually thereafter for a minimum period of 5 years.

RECENT CHANGES IN STTR LEGISLATION

The STTR Program has been reauthorized (P.L. 107-50) through 2009. The authorizing STTR legislation requires two significant programmatic changes:

- ***Change in STTR Agency Set-Aside Amounts and STTR Award Amounts.*** Beginning in fiscal year 2004, the STTR set-aside percentage will double from 0.15% to 0.30%. The statutory guideline for Phase II STTR awards will increase from $500,000 to $750,000.These changes apply to applications submitted for the April 1 (for awards made after September 30, 2003), August 1 and December 1 receipt dates.

- ***Phase II Data Collection Requirement.*** Each Phase II applicant will be required to provide information for the Small Business Administration Tech-Net Database System. See the section above under SBIR entitled "Phase II Data Collection Requirement" for more information.

ANIMAL STUDIES

The Institutional Animal Care and Use Committee (IACUC) verification of approval of proposed research involving Vertebrate Animals is not required at the time of application. It may be submitted with the application or in a "just-in-time" fashion prior to award (as is now permitted for IRB approval). Additional information is available from the following NIH Guide Notice: http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html. As part of the review process, the Scientific Review Group will continue to address the adequacy of animal usage and protection in applications; however, verification of IACUC review and approval may be submitted just prior to award. Therefore, be sure to address the points under "Vertebrate Animals" in your Research Plan.

SBIR/STTR LISTSERV

To get timely information about the SBIR/STTR Programs, send an email to LISTSERV@LIST.NIH.GOV with the following text in the message body: *subscribe SBIR-STTR <your name>* (e.g., *subscribe SBIR-STTR Jane Doe*). (The LISTSERV will retrieve your email address from the "From:" section of your email message.)

COLLABORATION OPPORTUNITIES AND RESEARCH PARTNERSHIPS (CORP)

Are you in need of a collaborator or researcher with specific scientific expertise to work on an SBIR/STTR project? The purpose of this site is to foster collaborative opportunities related to the SBIR/STTR Programs. If you are looking for a research partner or looking to partner with a small research firm, visit http://grants1.nih.gov/cfdocs/corp/add.htm to submit your needs or capabilities. Submissions considered appropriate for this site will be added to the CORP list (http://grants1.nih.gov/grants/funding/corp.htm).

CLARIFICATION OF BUDGET INSTRUCTIONS

The SBIR/STTR budget instructions have been extensively rewritten. In addition, a summary chart of the necessary forms for SBIR and STTR is included at the beginning of the Budget Instructions. Use this chart to ensure that you have submitted the correct forms appropriate to your specific type of application.

NON-COMPETING GRANT PROGRESS REPORTS

(http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-066.html)

Phase II SBIR/STTR awardees should be aware of the following information regarding submission of your Non-Competing Grant Progress Report (PHS 2590). NIH continues to transition the notification of Non-Competing Grant Progress Reports from a hard copy mailing of preprinted electronic PHS 2590 face pages to an electronic format. As discussed in the May 2, 2002 Notice on this topic (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-047.html), the last hard copy mailing of pre-printed face pages was mailed in late June 2002 for those progress reports with November 2002 start dates.

Beginning with December 2002 start dates and beyond; e.g., those progress reports due on/after October 1, 2002, grantees will need to access a website to determine which progress reports are due. Progress reports should continue to be mailed directly to the NIH awarding Institute/Center. A list of Institute/Center mailing addresses for progress reports is found at: http://grants.nih.gov/grants/type5_mailing_addresses.htm.

REMINDERS

FORMS

Phase II SBIR and STTR applications must be submitted using the Public Health Service Grant Application (PHS 398) in accordance with the Specific SBIR/STTR Grant Application Instructions and Requirements *described in these Phase II instructions and in the PHS 398 instructions*.

RECEIPT DATES

Phase II grant applications submitted *in response to the SBIR/STTR Omnibus Grant Solicitation* will be considered *"on time" if received by or mailed on or before the published receipt date and a proof of mailing is provided*. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark or a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable.

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH requires education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Information about this policy may be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Frequently Asked Questions (http://grants.nih.gov/grants/policy/hs_educ_faq.htm) regarding this policy are also included in this Guide Announcement.

SPECIAL ANNOUNCEMENTS

(*Program Announcements [PAs]/Requests for Applications [RFAs] for Small Business Research Opportunities* [http://grants1.nih.gov/grants/funding/sbir_announcements.htm])

In addition to the Omnibus Solicitation for NIH, CDC and FDA SBIR/STTR Grant Applications, you are encouraged to subscribe to the *NIH Guide for Grants and Contracts* to learn of new and emerging research interests. To receive weekly content notifications via email, subscribe to the NIH Guide Table of Contents Notification LISTSERV service (http://grants.nih.gov/grants/guide/listserv.htm). Note that receipt dates for applications submitted in response to specific PAs and RFAs may differ from the standard receipt dates.

PHASE III

The competition for SBIR/STTR Phase I and Phase II awards satisfies any competition requirement of the Armed Services Procurement Act, the Federal Property and Administrative Services Act, and the Competition in Contracting Act. Therefore, an agency that wishes to fund an SBIR/STTR Phase III project is not required to conduct another competition in order to satisfy those statutory provisions. As a result, in conducting actions relative to a Phase III SBIR/STTR award, it is sufficient to state for purposes of a Justification and Approval pursuant to FAR 6.302-5 that the project is a SBIR/STTR Phase III award that is derived from, extends, or logically concludes efforts performed under prior SBIR/STTR funding agreements and is authorized under 10 U.S.C. 2304(b)(2) or 41 U.S.C. 253(b)(2).

CONTACTS FOR MORE INFORMATION

TELEPHONE NUMBER FOR NIH STAFF PERSON

NIH Directory and Email Forwarding Service website: http://directory.nih.gov
Telephone: (301) 496-4000 (NIH locator)

NIH EXTRAMURAL RESEARCH PROGRAMS (GENERAL INFORMATION)

Grants pages of the NIH website: http://grants.nih.gov/grants/oer.htm
Email: GrantsInfo@nih.gov
Telephone: (301) 435-0714

HUMAN SUBJECT PROTECTIONS, INSTITUTIONAL REVIEW BOARDS, OR RELATED ASSURANCES

Office for Human Research Protections (OHRP) website: http://ohrp.osophs.dhhs.gov/index.htm
Telephone: (301) 496-7041

ANIMAL WELFARE, INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES (IACUC) AND RELATED REGULATIONS AND ASSURANCES

Office of Laboratory Animal Welfare (OLAW) website: http://grants.nih.gov/grants/olaw/olaw.htm
Telephone: (301) 496-7163

RECEIPT AND REFERRAL OF AN APPLICATION OR INADVERTENT OMISSION OF APPLICATION FORMS/PAGES AT THE TIME OF SUBMISSION

Division of Receipt and Referral, Center for Scientific Review
Telephone: (301) 435-0715
Fax: (301) 480-1987

SPECIFIC APPLICATION, BEFORE REVIEW

Telephone or email the Scientific Review Administrator named on your electronic "notification of assignment."

SPECIFIC APPLICATION, AFTER REVIEW

Telephone or email the Program Director named on your Summary Statement.

FACILITIES AND ADMINISTRATIVE (F&A)/INDIRECT COSTS

Division of Financial Advisory Services (DFAS) website: http://ocm.od.nih.gov/dfas/dfas.htm
Telephone: 301-496-2444

AUDIT REQUIREMENTS

Division of Financial Advisory Services (DFAS) website: http://ocm.od.nih.gov/dfas/dfas.htm
Telephone: 301-496-2494

I. INVITATION TO APPLY FOR SBIR/STTR PHASE II GRANT SUPPORT AND RELATED INFORMATION

The purpose of this Solicitation is to invite domestic small business concerns that have received an SBIR Phase I grant or an STTR Phase I grant to apply for SBIR or STTR Phase II funding, respectively, of that program. The objective of Phase I—the principal research and development (R&D) phase—is to continue the research efforts initiated in Phase I. Funding for Phase II is based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. An SBIR/STTR Phase I award must have been received in order to obtain a Phase II award. An SBIR Phase II award may be issued by a Federal agency other than the one that made the Phase I award. The Phase I and Phase II agencies should document their files appropriately, providing clear rationale for the transfer of the Phase II proposal to, and award by, the funding Federal agency.

A. Phase I Final Report, Financial Status Report and Commercialization Plan

PHASE I FINAL REPORT

Phase I grantees that (1) do not intend to seek Phase II support or (2) are not prepared to submit a Phase II application within four months following the expiration of the Phase I budget period, must submit a final report of their Phase I effort. *One original and two copies of the final report should be submitted to the Grants Management Officer identified on the Phase I Notice of Grant Award within 90 days of the expiration of the Phase I budget period*.

The Phase I report serves as an important source of material for staff of the awarding component in preparing annual reports, for planning purposes, and in communicating scientific accomplishments achieved through the SBIR/STTR program.

There is no "form page" for the Phase I Final Report. It may be typed on plain white paper (or you may use the PHS 398 Continuation Page). *The recommended length for the narrative portion is 10 pages*. See the instructions for completion of the "Research Plan" regarding the presentation of the accomplishments of the Phase I effort.

The format for the Phase I Final Report is as follows:

1. State the beginning and ending dates for the period covered by the SBIR Phase I grant.
2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.
3. Summarize the specific aims of the Phase I grant and provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims of Phase I since the project was initiated.
4. List the titles and complete references to publications, manuscripts *accepted* for publication, patents, invention reports, and other printed materials, if any, that have resulted from the Phase I effort. Submit five copies of such items, except patent and invention reports, as an *Appendix*.

Discussion with and further information on completion of the report may be obtained from the program official listed on the Phase I Notice of Grant Award.

FINANCIAL STATUS REPORT

A Financial Status Report (expenditures report) is required of all Phase I grantee organizations within 90 days of the expiration of the Phase I budget period. The Financial Status Report (FSR 269) form is available electronically at http://www.whitehouse.gov/OMB/grants/index.html. The form should be submitted independently of either a Phase I Final Report or a Phase II application. It must indicate the exact balance of any unobligated funds. No award for Phase II support may be made until the Financial Status Report for Phase I is received and approved by the awarding component.

Phase I grantees may request no-cost time extensions to complete their Phase I effort. Requests for such extensions must be made in writing to and approved by the Grants Management Officer of the awarding component. Requests must state the reasons for the extension and be submitted before the expiration of the Phase I budget period.

COMMERCIALIZATION PLAN

All Phase II applications must include a succinct Commercialization Plan (formerly Product Development Plan [PDP]). Specific details for preparing this section are described later in this solicitation.

B. Amount and Period of Support

PHASE II: Full R/R&D Effort
~ $750,000 (SBIR)
~ $500,000 (STTR)
~ 2 Years
Commercialization Plan
Submit within 2 years of end of Phase I

SBIR and STTR Phase II awards normally may not exceed $750,000 total (direct costs, F&A costs, and profit/fee) for a period normally not to exceed 2 years (see "Recent Changes in STTR Legislation"). However, these award levels for time and amount are statutory guidelines, not ceilings. Therefore, you are encouraged to propose a reasonable budget and project period that is appropriate for completion of the research project. Deviations from the guidelines are acceptable, *but must be well justified. You are encouraged to discuss budgetary deviations with NIH program staff prior to submission of the application*.

Only Phase I grantees are eligible to obtain Phase II funding. This includes those awardees identified via a "successor-in-interest" or "novated" or similarly-revised funding agreement, or those that have reorganized with the same key staff, regardless of whether they have been assigned a different tax identification number. Agencies may require the original awardee to relinquish its rights and interests in an SBIR/STTR project in favor of another applicant as a condition for that applicant's eligibility to participate in the SBIR Program for that project.

You may submit a Phase II application either before or after expiration of the Phase I budget period. *To maintain eligibility to seek Phase II support, a Phase I grantee organization should submit a Phase II application within the first six receipt dates following the expiration of the Phase I budget period*.

Only one Phase II award may be made for a single SBIR/ STTR project.

Under special circumstances, requests for supplemental funds to existing NIH SBIR/STTR grants or requests for an extension of the period of support with funds may be considered. (*The awarding of supplemental funds applies to NIH ONLY, as CDC and FDA do not make awards greater than the stated guidelines*.)

COMPETING SUPPLEMENTS

A competing supplemental application may be submitted under certain well-justified circumstances to request support for a significant expansion of a project's scope or research protocol. Applications for competitive supplements are not appropriate when the sole purpose is to restore awards to the full Scientific Review Group recommended level if they were administratively reduced by the funding agency. A supplemental application will not be accepted until after the original application has been funded, and it may not extend beyond the term of the current grant. *Applications for competitive supplements must be discussed with NIH program staff prior to submission*.

C. SBIR/STTR Program Eligibility

Each organization submitting an SBIR/STTR Phase II grant application must qualify as a small business concern (SBC) for R/R&D purposes *at the time of award*. In addition, under the SBIR program, the *primary employment of the Principal Investigator (PI)* must be with the *small business concern at the time of award and during the conduct of the proposed project*, unless otherwise approved in writing by the funding agreement officer after consultation with the NIH SBIR/STTR Program Coordinator. Also, the SBIR/STTR R/R&D work must be performed in the United States unless otherwise approved in writing by the funding agreement officer after consultation with the NIH SBIR/STTR Program Coordinator.

SBIR/STTR Eligibility Checklist

- ☑ **For- profit U.S. business firm.**
- ☑ **At least 51% U.S.-owned and independently operated.**
- ☑ **Small Business located in the U.S.**
- ☑ **Principal Investigator's primary employment with small business during project (SBIR only).**
- ☑ **500 or fewer employees.**
- ☑ **Small business concern is ALWAYS the applicant organization (SBIR or STTR application).**

The following sections provide more details about these eligibility criteria.

ORGANIZATIONAL CRITERIA

A small business concern is one that, for both Phase I and Phase II agreements, meets all of the following criteria:

1. Is organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor;
2. Is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there can be no more than 49 percent participation by foreign business entities in the joint venture;
3. Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States; and
4. Has, including its affiliates, not more than 500 employees. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a) and the term "number of employees" is defined in 13 CFR 121.3-2(t).

Business concerns, other than licensed investment companies, or State development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other, or (b) a third-party/parties controls or has the power to control both.

One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees and/or other facilities (e.g., laboratory space). Although access to special facilities or equipment in another organization is permitted (as in cases where the awardee organization has entered into a subcontractual agreement with another organization for a specific, limited portion of the research project, *research space occupied by an SBIR/STTR awardee organization must be space that is available to and under the control of the SBIR/STTR awardee for the conduct of its portion of the proposed project*. Title 13 CFR 121.3 also states that control or the power to control exists when "key employees of one concern organize a new concern ... and serve as its officers, directors, principal stockholders, and/or key employees, and one concern is furnishing or will furnish the other concern with subcontracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise." Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether such sharing constitutes control or the power to control.

For purposes of the SBIR Program, personnel obtained through a professional employer organization or other similar personnel leasing company may be considered employees of the awardee. This is consistent with SBA's size regulations, 13CFR 121.106 – Small Business Size Regulations.

Further information may be obtained by contacting the Small Business Administration (SBA) Size District Office at http://www.sba.gov/size/.

All SBIR/STTR grant applications will be examined with the above eligibility considerations in mind. If it appears that an applicant organization does not meet the eligibility requirements, we will request a size determination of your organization by the SBA. Under the circumstances in which eligibility is unclear, we will not make an SBIR or STTR award until the SBA provides a determination.

Note from the SBA about wholly-owned subsidiaries: The express terms of §121.702(a) require that the owners of the SBIR participant be "individuals" who are "citizens of, or permanent resident aliens in, the United States." The regulations nowhere provide that corporations or artificial entities may qualify as "individuals" who are U.S. citizens, nor do they suggest that indirect ownership of an SBIR/STTR participant by a U.S. citizen satisfies the ownership requirements of § 121.702(a).

Example 1. An applicant to the SBIR/STTR Program is owned 100% by Company A. Company A is owned 100% by U.S. citizens. The applicant is *not eligible* for the program because it is not directly owned and controlled 51% by citizens of or permanent resident aliens in the United States.

Example 2. An applicant to the SBIR/STTR Program is owned 51% by U.S. citizens and permanent resident aliens of the United States and 49% by a corporation. The applicant *is eligible* for the program, assuming it meets the other eligibility requirements (such as size) because 51% of the ownership rests directly with U.S. citizens and permanent resident aliens of the United States.

PRINCIPAL INVESTIGATOR CRITERIA

SBIR

Routinely, the primary employment of the Principal Investigator (PI) must be with the small business concern *at the time of award and during the conduct of the proposed project*. Primary employment means that more than one half of the PI's time is spent in the employ of the small business concern. *Primary employment with a small business concern precludes full-time employment at another organization*.

As defined in 42 CFR 52, the PI is the "single individual designated by the grantee in the grant application … who is responsible for the scientific and technical direction of the project." When the proposed PI clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation.

If the application has the likelihood for funding, the awarding component will require documentation to verify the eligibility of the PI, if at the time of submission of the application, the PI is a less-than-full-time employee of the small business concern, is concurrently employed by another organization, or gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

If the PI is employed or appears to be employed by an organization other than the applicant organization in a capacity such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate, a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant small business concern, the PI is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the PI is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

This requirement applies also to those individuals engaged currently as the PI on an active SBIR project. All current employment and all other appointments of the PI must be identified in his or her "Biographical Sketch" required as part of the application. Be certain that correct beginning and ending dates are indicated for each employment record listed.

STTR

The PI must commit a minimum of 10% effort to the project and the PI must have a formal appointment with or commitment to the applicant small business concern, which is characterized by an official relationship between the small business concern and that individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the PI's official relationship with the grantee must entail sufficient opportunity for the PI to carry out his or her responsibilities for the overall scientific and technical direction of the project. *Documentation describing the official relationship of the PI with the applicant small business concern should NOT be submitted with the grant application, but a copy must be furnished upon the request of the NIH awarding component*.

Signatures on the Face Page and the Research Institution budget page certify that the Principal Investigator has a formal relationship with/commitment to the small business concern.

The following are examples of situations describing the official relationship of the PI with the applicant small business organization:

- PI with a full-time, university appointment may also have appointments with other organizations (with or without salary) and still appropriately consider his or her commitment to the university to be "full-time," consistent with the personnel policies and procedures of the university applied on a routine basis. The PI's commitment to the university and other organizations (including the applicant small business concern) cannot exceed 100% of his or her total professional effort.

- PI with a full-time, 12-month appointment with a small business concern would be considered to have a commitment to the applicant organization of 100% of his or her total professional effort.

- PI who has a part-time appointment with a small business concern and has concurrent commitments or appointments with organizations in addition to the small business concern would deem each commitment as a portion of 100% of his or her total professional effort.

As responsible stewards of funds, the NIH is concerned that the PI has the time available to carry out the proposed STTR research activities. Therefore, it should be clear on the application that the time proposed for the PI on a particular project is reasonable and it should be clear that the PI has sufficient time (*minimum 10% effort*) from among his or her total professional commitments to devote to this project.

The PI should be paid by either the research institution or the small business, not both. Therefore, the PI's name should not be listed on both the small business and the research institution budget pages.

The *NIH Grants Policy Statement* requires all grantees to establish safeguards to prevent any individuals who are involved in grant-supported activities from using their position for private financial gain for themselves, family members, or organizations with which they have financial ties, such as an employer.

The following example may raise concerns about the impartiality of individuals who are involved in grant-supported activities: The PI (or co-PI) is an employee at the research institution and the President/CEO of the small business. All research activities are proposed to be conducted in the PI's lab at the university with "300 sq. ft. in one of the PI's labs dedicated" for research conducted by the small business (e.g., one employee, post-doc). The possible conflict raised by this example is that the Principal Investigator or other employee of the collaborating research institution who also serves as the business official for the small business could appear to lack impartiality. The business official might appear to be acting without sufficient independence from his or her employer, the collaborating institution, which could possibly result in improper financial gain for the collaborating institution. To address this concern, the small business could appoint someone who is not an employee of the collaborating institution to serve as the business official.

CONTRACTUAL ARRANGEMENTS AND PERFORMANCE OF RESEARCH AND ANALYTICAL WORK BY THE APPLICANT ORGANIZATION

SBIR

In Phase II, normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. The total amount of consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct, indirect, and fee).

The signature of the authorized organizational official on the Face Page signifies that the applicant and all proposed consortium participants understand and agree to the following statement:: *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy*.

The basis for determining the percentage of work to be performed by each of the cooperative parties in Phase II will be the total of direct and indirect costs attributable to each party, *unless otherwise described and justified in the "Contractual Arrangements" portion of the Research Plan section of the application*.

STTR

The small business concern is always the applicant/ awardee organization on an STTR.

In Phase I and Phase II, at least 40% of the work must be performed by the small business concern and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of direct and F&A/indirect costs attributable to each party, *unless otherwise described and justified in the "Contractual Arrangements" portion of the Research Plan section of the application*.

Certification showing the cooperative R&D arrangement must be submitted with the application using the STTR Research Institution Budget Form Page (Non-Modular STTR Applications) or STTR Research Institution Certification Format Page (Modular STTR Applications).

This certification is different than the "Model Agreement, Small Business Technology Transfer (STTR) Program, Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-on Research, Development, or Commercialization," which is required to receive support under the STTR Program but is *NOT* submitted with the application. *By signing the Face Page of the grant application, the Official Signing for Applicant Organization (small business concern) certifies that the Agreement with the research institution will be effective at the time of award*. A copy of the Agreement must be furnished upon request of the NIH awarding component.

RESEARCH FACILITIES

The research and analytical work performed by the grantee organization is to be conducted in research space occupied by, available to, and under the control of the SBIR/STTR grantee for the conduct of its portion of the proposed project. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR/STTR awardee has entered into a sub-contractual agreement with another institution for a specific, limited portion of the research project.

Whenever a proposed SBIR/STTR project is to be conducted in facilities other than those of the applicant organization, and if the application has the likelihood for funding, the awarding component will request that the small business concern provide a letter from the organization stating that leasing/rental arrangements have been negotiated for appropriate research space. This letter, to be signed by an authorized official of the organization whose facilities are to be used for the SBIR/STTR project, must certify that the small business concern (awardee organization) will have access to and control over the research space. In addition, the letter must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the grantee organization. This letter, if included with the application, is excluded from the page limitations.

PERFORMANCE SITE CRITERIA

The SBIR/STTR research or R&D project activity must be performed in its entirety in the United States. In those rare circumstances that necessitate the use of foreign sites because of the study design (e.g., patient populations), investigators must thoroughly justify the use of these sites in the application. Similarly, in those rare circumstances that necessitate the purchase of materials from other countries, investigators must thoroughly justify the request. These rare and unique situations will be considered on a case-by-case basis, and they should be discussed with NIH staff prior to submission of the application. Approval by the funding officer for such specific condition(s) must be in writing prior to issuance of an award. Whenever possible, other work outside of the United States, which is necessary to the overall completion of the project, should be supported by non-SBIR/STTR funds.

D. Similarities and Differences Between SBIR and STTR

SBIR and STTR are similar in that these programs are three-phased, both seek to increase the participation of small businesses in Federal R&D, and both seek to increase private sector commercialization of technology developed through Federal R&D. There are two major differences between these programs:

1. The STTR program *requires* that a small business concern formally partner with a non-profit research institution in the collaborative conduct of a project that has potential for commercialization. To be eligible for an STTR award, at least 40% of the work must be performed by the small business, and at least 30% of the work must be performed by a U.S. non-profit research institution through a formal cooperative R&D arrangement. Such institutions include universities, non-profit hospitals, and other non-profit organizations as well as Federally-funded research and development centers. (The same requirement is applicable for both Phase I and Phase II.)

   The SBIR program does not have this requirement; therefore, the small business concern may conduct the entire SBIR project without outside collaboration.

   STTR grants are awarded to the small business, which will receive all funding for the project and disperse the appropriate funds to the research institution.

2. The SBIR program *requires* that the primary employment of the Principal Investigator (greater than 50% of his/her time) be with the small business concern at the time of award and during the project period. Unlike SBIR, primary

SBIR and STTR Comparison

REQUIREMENTS	SBIR	STTR
Applicant Organization	Small Business Concern (SBC)	Small Business Concern (SBC)
Award Period*	Phase I – 6 months, normally Phase II – 2 years, normally	Phase I – 1 year, normally Phase II – 2 years, normally
Award Dollar Guidelines*	Phase I – $100,000, normally Phase II – $750,000, normally	Phase I – $100,000, normally Phase II – $750,000, normally
Principal Investigator	Employed by company more than 50% of his/her time *during* award. Minimum level of effort on the project not stipulated.	Employment not stipulated. The PI must spend a minimum of 10% effort on the project and have a formal appointment with or commitment to the SBC.
Subcontract/Consultant Costs*	Phase I – Total amount of contractual and consultant costs normally may not exceed 33% of total amount requested. Phase II – Total amount of contractual and consultant costs normally may not exceed 50% of total amount requested.	Phase I and Phase II – SBC must perform at least 40% of work and the single, partnering U.S. non-profit research institution must perform at least 30% of the work.
Performance Site	Must be entirely in U.S.* Part of research must take place in company-controlled research space.	Must be entirely in U.S.* Part of research must take place in company-controlled research space and part in that of partnering U.S. research institution.

**Deviations permissible with written justification and approval.*

employment of the PI with the small business concern is not stipulated under the STTR Program. Therefore, the PI on an STTR project may be from the small business concern or the research institution as long as he/she has a *formal official relationship with or commitment to the applicant small business concern*.

For a more detailed comparison of the SBIR and STTR programs, refer to the "SBIR and STTR Comparison" table above.

Applications proposing essentially the same project will not be accepted for review under both the STTR and SBIR programs.

II. AGENCY INFORMATION

The SBIR/STTR Phase II Grant application instructions and forms are available electronically at http://grants.nih.gov/grants/funding/sbir.htm.

A. Program Officials/Agency Contact Information

Applicants are strongly encouraged to contact NIH program staff prior to submitting an SBIR/STTR grant application. Questions regarding grant administration and business management should be directed to the Grants Management staff (see "Awarding Component Contact Information" table below).

Questions of a general nature about the NIH SBIR/STTR program should be directed to:

Ms. Jo Anne Goodnight
NIH SBIR/STTR Program Coordinator
6705 Rockledge Drive
Rockledge I, Room 3534
Bethesda, MD 20892
Phone: 301-435-2688, Fax: 301-480-0146
Email: sbir@od.nih.gov or jg128w@nih.gov

Ms. Kay Etzler
NIH SBIR/STTR Program Analyst
6705 Rockledge Drive
Rockledge I, Room 3522
Bethesda, MD 20892
Phone: 301-435-2713, Fax: 301-480-0146
Email: sbir@od.nih.gov or etzlerk@od.nih.gov

PHS SBIR/STTR Solicitation Office
13685 Baltimore Avenue
Laurel, MD 20707-5096
Phone: (301) 206-9385, Fax: (301) 206-9722
Email: sbirsttr@peacetech.com

The following table includes points of contact information for each PHS awarding component. More detailed information on each of the NIH awarding components, as well as the CDC and FDA, are available electronically on the home pages cited in the table and in Part II – NIH, CDC, and FDA Program Descriptions and Research Topics (PDF or MS Word) of the solicitation.

B. Awarding Component Contact Information

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Institute on Aging http://www.nia.nih.gov	Dr. Michael-David ARR Kerns Phone: 301-496-9322 Fax: 301-402-2945 Email: kernsm@nia.nih.gov	Ms. Linda Whipp Phone: 301-496-1472 Fax: 301-402-3672 Email: lw17m@nih.gov
National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Dr. Karen Peterson Phone: 301-451-3883 Fax: 301-443-6077 Email: kpeterso@mail.nih.gov	Ms. Judy Simmons Phone: 301-443-2434 Fax: 301-443-3891 Email: js182a@nih.gov
National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov	Dr. Gregory Milman Phone: 301-496-8666 Fax: 301-402-0369 Email: gmilman@niaid.nih.gov	Ms. Mary Kirker Phone: 301-496-70750775 Fax: 301-480-3780 Email: mk35h@nih.gov
National Institute of Arthritis and Musculoskeletal and Skin Diseases http://www.niams.nih.gov/	Dr. Cheryl Kitt Phone: 301-594-2463 Fax: 301-480-4543 Email: kittc@mail.nih.gov	Ms. Melinda Nelson Phone: 301-435-5278 Fax: 301-480-5450 Email: mn23z@nih.gov
National Institute of Biomedical Imaging and Bioengineering http://www.nibib.nih.gov/	Dr. Joan T. Harmon Phone: 301-451-6772 Fax: 301-480-4515 Email: joan_harmon@nih.gov	Ms. Annette Hanopole Phone: 301-451-6768 Fax: 301-480-4515 Email: ah23k@nih.gov
National Cancer Institute http://www.nci.nih.gov or http://www.cancer.gov	Ms. Connie Dresser Phone: 301-435-2846 Fax: 301-480-2087 Email: cd34b@nih.gov	Mr. Shane Woodward Phone: 301-496-8649 Fax: 301-496-8601 Email: sw200e@nih.gov
National Institute of Child Health and Human Development http://www.nichd.nih.gov	Dr. Louis A. Quatrano Phone: 301-402-4221 Fax: 301-402-0832 Email: lq2n@nih.gov	Ms. Diane Watson Phone: 301-435-6975 Fax: 301-402-0915 Email: dw40j@nih.gov
National Institute on Drug Abuse http://www.nida.nih.gov	Dr. Cathrine Sasek Phone: 301-443-6071 Fax: 301-443-6277 Email: csasek@nih.gov.	Mr. Gary Fleming Phone: 301-443-6710 Fax: 301-594-6849 Email: gf6s@nih.gov

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Institute on Deafness and Other Communication Disorders http://www.nidcd.nih.gov	Dr. Lynn E. Luethke Phone: 301-402-3458 Fax: 301-402-6251 Email: lh99s@nih.gov	Ms. Sara Stone Phone: 301-402-0909 Fax: 301-402-1758 Email: sara_stone@nih.gov
National Institute of Dental and Craniofacial Research http://www.nidcr.nih.gov	Dr. Jaya Satish Phone: 301-594-4861 Fax: 301-480-8318 Email: js824m@nih.gov	Ms. Mary Daley Phone: 301-594-4808 Fax: 301-480-8303 Email: md74u@nih.gov
National Institute of Diabetes and Digestive and Kidney Diseases http://www.niddk.nih.gov	Dr. Judith Podskalny Phone: 301-594-3197 Fax: 301-480-8300 Email: jp53s@nih.gov	Ms. Teresa Farris Marquette Phone: 301-594-3197 Fax: 301-480-3504 Email: tf102y@nih.gov
National Institute of Environmental Health Sciences http://www.niehs.nih.gov	Dr. Jerrold Heindel Phone: 919-541-0781 Fax: 919-541-5064 Email: heindelj@niehs.nih.gov	Ms. Carolyn Winters Phone: 919-541-7823 Fax: 919-541-2860 Email: winters@niehs.nih.gov
National Eye Institute http://www.nei.nih.gov	Dr. Ralph Helmsen Phone: 301-496-5301 Fax: 301-402-0528 Email: rh27v@nih.gov	Ms. Chris Davis Phone: 301-435-8177 Fax: 301-496-9997 Email: cad@nei.nih.gov
National Institute of General Medical Sciences http://www.nigms.nih.gov/	Dr. Peter Preusch Phone: 301-594-5938 Fax: 301-480-2802 Email: preuschp@nigms.nih.gov	Ms. Linda Roberts Phone: 301-594-5141 Fax: 301-480-2554 Email: lr24v@nih.gov
National Heart, Lung, and Blood Institute http://www.nhlbi.nih.gov	Dr. John T. Watson Phone: 301-435-0513 Fax: 301-480-1336 Email: jw53f@nih.gov	Ms. Suzanne White Phone: 301-435-0144 Fax: 301-480-3310 Email: sw52h@nih.gov
National Human Genome Research Institute http://www.genome.gov	Dr. Bettie J. Graham Phone: 301-496-7531 Fax: 301-480-2770 Email: bg30t@nih.gov	Ms. Jean Cahill Phone: 301-435-7858 Fax: 301-402-1951 Email: jc166o@nih.gov
National Institute of Mental Health http://www.nimh.nih.gov	Dr. Michael F. Huerta Phone: 301-443-3563 Fax: 301-443-1731 Email: mhuerta@helix.nih.gov	Ms. Kathy Hancock Phone: 301-496-5482 Fax: 301-402-0915 Email: kh47d@nih.gov
National Institute of Neurological Disorders and Stroke http://www.ninds.nih.gov	Dr. Thomas Miller Phone: 301-496-1779 Fax: 301-402-1501 Email: tm208y@nih.gov	Ms. Kathleen Howe Phone: 301-496-9231 Fax: 301-402-0219 Email: kh52x@nih.gov
National Institute of Nursing Research http://www.nih.gov/ninr	Dr. Hilary Sigmon Phone: 301-594-5970 Fax: 301-480-8260 Email: hs38k@nih.gov	Ms. Cindy McDermott Phone: 301-594-6869 Fax: 301-402-4502 Email: cm253t@nih.gov

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Center for Research Resources http://www.ncrr.nih.gov	Dr. Louise E. Ramm Phone: 301-435-0879 Fax: 301-480-3658 Email: lr34m@nih.gov	Ms. Kimberly Pendleton Phone: 301-435-0845 Fax: 301-480-3777 Email: kp190i@nih.gov
National Center for Complementary and Alternative Medicine http://nccam.nih.gov	Dr. Shan Wong Phone: 301-496-7498 Fax: 301-480-3621 Email: sw196c@nih.gov	Mr. Marc Pitts Phone: 301-594-9095 Fax: 301-480-3621 Email: mp384x@nih.gov
National Center on Minority Health and Health Disparities http://www.ncmhd.nih.gov	Mr. Vincent A. Thomas, Jr. Phone: 301-402-2516 Fax: 301-480-4049 Email: vt5e@nih.gov	Mr. Bryan Clark Phone: 301-594-8412 Fax: 301-480-4049 Email: clarkb@od.nih.gov
National Library of Medicine http://www.nlm.nih.gov	Dr. Milton Corn Phone: 301-496-4621 Fax: 301-402-2952 Email: cornm@mail.nlm.nih.gov	Mr. Christopher Robey Phone: 301-496-4221 Fax: 301-402-0421 Email: jr58a@nih.gov
Centers for Disease Control and Prevention (CDC) http://www.cdc.gov	Mr. Curtis L. Bryant Phone: 770-488-2806 Fax: 770-488-2828 Email: ckb9@cdc.gov	Ms. Elmira Benson Phone: 770-488-2628 Fax: 770-488-2777 Email: ebenson@cdc.gov
Food and Drug Administration (FDA) http://www.fda.gov	Ms. Rosemary Springer Phone: 301-827-7182 Fax: 301-827-7106 Email: rspringe@oc.fda.gov	Ms. Peggy Jones Phone: 301-827-7160 Fax: 301-827-7106 Email: pjones@oc.fda.gov

III. DEFINITIONS

Applicant. The organizational entity that, at the time of award, will qualify as a Small Business Concern (SBC) and that submits a grant application for a funding agreement under the SBIR or STTR Program.

Affiliate. This term has the same meaning as set forth in 13 CFR Part 121 – Small Business Size Regulations, §121.103, *"What is affiliation?"*

Child. NIH defines a child as an individual under the age of 21 years. It should be noted that the definition of child described above will pertain notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age and varying definitions employed by some states. Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address the age at which a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Clinical Research. NIH defines human clinical research as: *(1)* Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. *(2)* Epidemiologic and behavioral studies. *(3)* Outcomes research and health services research.

Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

Clinical Trial. For purposes of reviewing applications submitted to the NIH, a clinical trial is operationally defined as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective. Clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

- *Phase I* clinical trials are done to test a new biomedical or behavioral intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., determine a safe dosage range, and identify side effects).
- *Phase II* clinical trials are done to study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
- *Phase III* studies are done to study the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.
- *Phase IV* studies are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
- *NIH-Defined Phase III Clinical Trial*. For the purpose of the Guidelines an NIH-defined Phase III "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Co-Investigator. A Co-Investigator (collaborator) is an individual involved with the Principal Investigator in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as key personnel. The individual(s) may be employed by, or affiliated with, either the grantee organization or an organization participating in the project under a consortium or contractual agreement.

Collaborator. An individual involved with the Principal Investigator in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as key personnel. The collaborator may be employed by, or affiliated with, either the grantee organization or an organization participating in the project under a consortium or contractual agreement.

Commercialization. The process of developing marketable products and/or services and producing and delivering products or services for sale (whether by the originating party or by others) to Government and/or commercial markets.

Consortium or Contractual Agreement. An agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. In this arrangement, the grantee contracts for the performance of a substantial and/or significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization's Principal Investigator and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including indirect costs.

Consultant. An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring party. Consultants may also include firms that provide paid professional advice or services.

Contract. An award instrument establishing a binding legal procurement relationship between a

funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to provide payment therefore.

Cooperative Agreement. A financial assistance mechanism to be used in lieu of a grant when substantial Federal programmatic involvement with the recipient during performance is anticipated by the PHS awarding component.

Employee. The number of employees of a firm is its average number of persons employed for each pay period over the firm's latest 12 months. Any person on the payroll must be included as one employee regardless of hours worked or temporary status. The number of employees of a firm in business under 12 months is based on the average for each pay period it has been in business.

Essentially Equivalent Work. This term is meant to identify "scientific overlap," which occurs when (1) substantially the same research is proposed for funding in more than one proposal (contract proposal or grant application) submitted to the same Federal agency; OR (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; OR (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

Expanded Authorities. The operating authorities provided to grantees under certain research grant mechanisms that waive the requirement for NIH prior approval for specified actions. See the *NIH Grants Policy Statement* http://grants1.nih.gov/grants/policy/nihgps_2001/part_iia_5.htm#_Toc504811854 and the *NIH Guide Notice* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-070.html) which expanded the authorities (other than Phase I carry-over) to include Phase I SBIR/STTR.

Facilities and Administrative (Indirect) Costs. Facilities and Administrative (F&A) Costs are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. See the Checklist Instructions and Checklist Form Page.

Feasibility. The practical extent to which a project is capable of being successfully performed.

Grant. A financial assistance mechanism whereby money and/or direct assistance is provided to carry out approved activities. A grant is used whenever the Federal agency anticipates no substantial programmatic involvement with the awardee during performance of the financially assisted activities.

Historically Underutilized Business Zone (HUBZone). A small business concern meeting the following criteria:

1. Located in a "historically underutilized business zone" or HUBZone area located in one or more of the following:
   a. A qualified census tract (as defined in section 42(d)(5)(C)(i)(I) of the Internal Revenue Code of 1986; or
   b. A qualified "non-metropolitan county" (as defined in section 143(k)(2)(B) of the Internal Revenue Code of 1986) with a median household income of less than 80 percent of the state median household income or with an unemployment rate of not less than 140 percent of the statewide average, based on U.S. Department of Labor recent data; or
   c. Lands within the boundaries of federally recognized Indian reservations.
2. Owned and controlled by one or more U.S. Citizens.
3. At least 35% of its employees must reside in a HUBZone.

Human Subjects. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations governing the inclusion of human subjects in research extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an

individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR 46.

Innovation. Something new or improved, having marketable potential, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of "innovation" would be new medical or biological products for improved value, efficiency, or costs.

Institutional Base Salary. The annual compensation that the applicant organization pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary may not be increased as a result of replacing institutional salary funds with grant funds.

Some PHS grant recipients are currently subject to a legislatively imposed salary limitation. *Effective January 1, 2003, the salary limitation (cap) is $171,900*. Any adjustment for salary limits will be made at time of award. Applicants are encouraged to contact their offices of sponsored programs or search the *NIH Guide for Grants and Contracts* for "salary cap" or "salary limitation" for current guidance on salary requirements.

Intellectual Property. The separate and distinct types of intangible property that are referred to collectively as "intellectual property," including but not limited to: patents, trademarks, copyrights, trade secrets, SBIR/STTR technical data (as defined in this section), ideas, designs, know-how, business, technical and research methods, and other types of intangible business assets, and including all types of intangible assets either proposed or generated by an SBC as a result of its participation in the SBIR Program.

Joint Venture. An association of persons or concerns with interests in any degree or proportion by way of contract, express or implied, consorting to engage in and carry out a single specific business venture for joint profit, for which purpose they combine their efforts, property, money, skill, or knowledge, but not on a continuing or permanent basis for conducting business generally. A joint venture is viewed as a business entity in determining power to control its management, has been assigned its own Employer Identification Number by the Internal Revenue Service, and is eligible under the SBIR Program provided that the entity created qualifies as an "SBC" as defined in this section.

Key Personnel Engaged on Project. This term is meant to identify those individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. *Consultants should also be included if they meet the definition of "key personnel*."

Principal Investigator. The one individual designated by the applicant organization to direct the project or program to be supported by the grant. The Principal Investigator is responsible and accountable for the proper conduct of the project or program.

Program Income. Gross income earned by a grant recipient during the budget period of the grant as a result of activities supported by the grant award. The *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps) contains a detailed explanation of program income, ways in which it may be generated and accounted for, and the various options for its use and disposition. Examples of program income include:

- Patent or copyright royalties.
- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing.
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds.
- Third-party patient reimbursement for hospital or other medical services, such as insurance

payments for patients when such reimbursement occurs because of the grant-supported activity.

- Funds generated by the sale of products developed under the grant, which include but are not limited to drugs, assays, devices, instrumentation, software, laboratory techniques/methodologies, and testing/training devices or systems.

- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals.

Generally, SBIR/STTR grantee organizations that earn program income may be authorized to have such income added to the grant account and used to further the objectives of the research project. Authorization must be requested from the Grants Management Officer of the appropriate PHS awarding component.

Prototype. A model of something to be further developed, which includes designs, protocols, questionnaires, software, and devices.

Research Institution. A United States research organization that is a:

1. Nonprofit college or university; OR
2. Nonprofit research institution, including nonprofit medical and surgical hospitals (a "nonprofit institution" is defined as an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual); OR
3. Contractor-operated, federally funded research and development center, as identified by the National Science Foundation in accordance with the Government-wide Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor legislation thereto).

(*Laboratories staffed by Federal employees do not meet the definition of "research institution" for purposes of the STTR program*.)

Research or Research and Development (R/R&D). Any activity that is a:

1. Systematic, intensive study directed toward greater knowledge or understanding of the subject studied; OR
2. Systematic study directed specifically toward applying new knowledge to meet a recognized need; OR
3. Systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

SBIR/STTR Technical Data. All data generated during the performance of an SBIR/STTR award.

SBIR/STTR Technical Data Rights. The rights a small business concern obtains in data generated during the performance of any SBIR/STTR Phase I, Phase II, or Phase III award that an awardee delivers to the Government during or upon completion of a Federally-funded project, and to which the Government receives a license.

Small Business Concern. A small business concern is one that, *on the date of award* for both Phase I and Phase II agreements, meets all of the following criteria:

1. Is organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor;
2. Is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there can be no more than 49 percent participation by foreign business entities in the joint venture;
3. Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States; and
4. Has, including its affiliates, not more than 500 employees.

In the case of a publicly owned business, at least 51% of the small business voting stock must be owned by U.S. citizens or lawfully admitted permanent resident aliens.

Business concerns, other than licensed investment companies, or State development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both. Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t).

Further information may be obtained by contacting the Small Business Administration Size District Office at http://www.sba.gov/size/.

Socially and Economically Disadvantaged Individual. A member of any of the following groups:

1. Black Americans.
2. Hispanic Americans.
3. Native Americans.
4. Asian Pacific Americans.
5. Subcontinent Asian Americans.
6. Other groups designated from time to time by SBA to be socially disadvantaged; or any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

Socially and Economically Disadvantaged Small Business Concern. See 13 CFR Part 124 – 8(A) Business Development/Small Disadvantaged Business Status Determinations, §124.103 ("Who is socially disadvantaged?") and §124.104 ("Who is economically disadvantaged?")

Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by an awardee of a funding agreement calling for supplies or services required solely for the performance of the prime contract or another subcontract.

United States. The 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

Women-Owned Small Business Concern. A small business concern that is at least 51% owned by one or more women, or in the case of any publicly owned business, at least 51% of the stock is owned by women, and women control the management and daily business operations. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

IV. PHASE II GRANT APPLICATION INSTRUCTIONS AND REQUIREMENTS

Your SBIR/STTR application should represent a sound approach to the investigation of an important biomedical research, behavioral research, technological, engineering or scientific question, and be worthy of support under the stated criteria of this program solicitation. It should be self-contained and written with the care and thoroughness accorded to papers for publication.

Review the application carefully to ensure that information essential for evaluation is included. The scientific and technical merit of the proposed research is the primary concern for all research supported by NIH, CDC and FDA. You are *strongly encouraged to contact agency program staff for pre-application guidance (particularly if you are submitting a revised application)*.

A firm must not propose market research, patent applications, or litigation. The research may be carried out through construction and evaluation of a laboratory prototype, where necessary.

A. Forms and Instructions

All SBIR and STTR applications (Phase I, Phase II, and Phase I/Phase II Fast-Track) must be submitted using the Public Health Service Grant Application Forms (PHS 398) in accordance with these instructions and the PHS 398 (HTML | PDF).

These instructions/requirements are based on the PHS 398.

The PHS 398 includes Form Pages *and* Format Pages. The Format pages are intended to *assist* in the development of specific sections of the application. Most of the Format Pages have been left "unprotected" to allow you to format text, insert

graphics, diagrams, or tables. Alternatively, you may create a page similar to the format provided and inclusive of requisite information.

The following PHS 398 forms (RTF | PDF) apply specifically to SBIR and STTR applicants:

FULL SET – (RTF | PDF)

INDIVIDUAL FORM FILES

- Form Page 1: Face Page (RTF | PDF)
- Form Page 2: Description, Performance Sites, and Key Personnel (RTF | PDF)
- Form Page 3: Research Grant Table of Contents (RTF | PDF)
- Form Page 4: Detailed Budget for Initial Budget Period (RTF | PDF)
- Form Page 5: Budget for Entire Proposed Period of Support (RTF | PDF)
- Modular Budget Format Page (RTF | PDF) (*for applications of $100,000 total costs or less*)
- Biographical Sketch Format Page (RTF | PDF)
- Resources Format Page (RTF | PDF)
- Checklist Form Page (RTF | PDF)
- Personal Data Form Page (RTF | PDF)
- Continuation Page (RTF | PDF)
- STTR Research Institution Budget Form Page (RTF | PDF)
- STTR Research Institution Certification Format Page (Modular STTR Only) (RTF | PDF)
- STTR Model Agreement (*to be submitted upon request by NIH staff, not with the application*)
- Research Plan: There is *no form page*.
- Targeted/Planned Enrollment Format Page (RTF | PDF) (*if human subjects research is proposed*)
- Enrollment Report Format Page (RTF | PDF) (*if human subjects research is proposed*)
- Mailing Address, RFA and SBIR/STTR Labels (RTF | PDF)

REMINDER SHEET

You are encouraged to refer to the appropriate SBIR Reminder Sheet or STTR Reminder Sheet to ensure that the requirements for submission have been met.

B. Limitations on Length of Application

PHASE II SBIR/STTR

Observe the page number limitations or the application may be significantly delayed in the review process.

- *Items a-d* of the Phase II Research Plan are limited to 25 pages.
- "Introduction" (required when submitting a revised application) is limited to three (3) pages.
- Biographical Sketch Format Page(s) is limited to a *maximum* of 4 pages for each key person.
- Commercialization Plan is limited to 15 pages.

There is no further limitation on the total number of pages for the entire Phase II application; however, applicants are encouraged to be succinct.

C. Type Size, Photographs, and Images

Type size specifications must be observed; if not, application processing may be delayed or the application may be returned to the applicant without review. Type requirements should be checked on the *printed document* using a standard device for measuring type size, rather than relying on the font selected for a particular word processor/printer combination.

FORMAT SPECIFICATIONS

Prepare the application, single-sided and single-spaced. Use black type that can be photocopied; do not use photo reduction. Use English only and avoid jargon and unusual abbreviations. Draw all graphs, diagrams, tables, and charts in black ink.

Font sizes on some of the PHS 398 form pages vary due to field or space limitations. The PHS 398 Rich Text File (RTF) and Portable Document File (PDF) Form pages as provided are acceptable by NIH. All other sections of your application (e.g., Biographical Sketch; Introduction, if necessary; Literature Citations; and the Research Plan) must conform to all of the following requirements:

1. The height of the characters must not be smaller than 10 points. *NIH-suggests* using a Helvetica or Arial, 12-point font (as using a 10-point font provides no guarantee that the type will satisfy the required specifications of characters per inch or lines per inch).
2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi). For proportional fonts, the average for any representative section of text must not exceed 15 cpi.
3. Type size used in figures, charts, tables, figure legends, and footnotes may be a smaller type size but *must* be readily legible.
4. There must be no more than 6 lines of type within a vertical inch.
5. All page margins (i.e., top, bottom, left and right), *including continuation page margins*, must be at least ½ inch.

Adherence to type size, type density, and vertical line spacing requirements is necessary for several reasons. No applicant should have an advantage over other applicants by providing more content in his/her application by using smaller, denser type. Small type sizes may also make it difficult for reviewers to read the application. See "Answers to FAQs About Grant Application Format" (http://grants1.nih.gov/grants/funding/sbirsttr1/FAQs_format.rtf).

NIH's Center for Scientific Review (CSR), Division of Receipt and Referral has the responsibility and authority to make the final determination of legibility; this decision is final and not appealable. Further inquiries should be directed to the:

CSR, Division of Receipt and Referral
Phone: (301) 435-0715; Fax: (301) 480-1987

PHOTOGRAPHS AND IMAGES

Do not include photographs or other materials that are not printed *directly* on the application page in the body of the application. Pictures or other materials that are pasted onto application pages are incompatible with the current duplication/scanning process. You may include black-and-white or color images in the six (6) submitted copies provided such images are *printed directly* on the application page and are critical to the content of the application.

You may submit pertinent photographs or other materials that cannot be photocopied as five collated sets as part of an appendix. In these circumstances, the original application must include black-ink images so as not to circumvent the page limitations for SBIR/STTR applications.

Applications not meeting all of these requirements may be significantly delayed in the review process.

D. Specific SBIR/STTR Grant Application Instructions and Requirements

1. FACE PAGE (RTF | PDF)

The information provided on the Face Page of the application and the fiscal information, including the calculation of F&A costs, must be verified by the official signing for applicant organization.

Item 1. Title of Project

Do not exceed 56 characters, including the spaces between words and punctuation. Choose a descriptive title that is specifically appropriate. *Ordinarily, the SBIR/STTR Phase II application should carry the same title as the Phase I grant*.

A competing continuation or revised application should ordinarily have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

Item 2. Response to Specific Request for Application (RFA) or Program Announcement (PA) or Solicitation

Check "Yes."

Number. Provide the number of the Phase I grant award (e.g., 1R43HL12345-01A1). If the application is submitted in response to an RFA or a PA issued through the NIH Guide for Grants and Contracts, identify the appropriate announcement number (e.g., PA-03-007). *Type "Fast-Track," if appropriate. Do not type PHS 398 in this line*.

Title. Type "Phase II SBIR" or "Phase II STTR," as appropriate.

If the application is submitted in response to an RFA or a PA issued through the *NIH Guide for Grants and Contracts*, check "Yes," and identify the appropriate announcement title of the PA or RFA.

Item 3. Principal Investigator

New Investigator. Check "Yes" in the "New Investigator" box only if the Principal Investigator has not previously served as such on any PHS-supported research project. *If the Principal Investigator is not a new investigator, check "No*."

Item 3a. Name of Principal Investigator

Name the *one* person responsible to the applicant small business concern for the scientific and technical direction of the project. *PHS staff conduct official business only with Principal Investigators and institutional officials*. A supplemental application *must* have the same Principal Investigator as the currently funded grant.

Reminder: Under the SBIR Program, routinely the primary employment (more than 50 percent time) of the Principal Investigator must be with the small business concern *at the time of award* and during the conduct of the proposed project. Under the STTR Program, primary employment with the small business concern is not stipulated.

Item 3b. Degrees

Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., R.N.).

Item 3c. Position Title

Provide the academic or professional title of the Principal Investigator/Program Director. If more than one title, indicate the one most relevant to the proposed project (e.g., Director of Research).

Item 3d. Mailing Address

Provide complete information (including room number, building, and street address) necessary for postal delivery. All written communications with the Principal Investigator will use this address. For electronic mail, enter the appropriate email address (not the website URL).

Item 3e. Department, Service, Laboratory, or Equivalent

Indicate your organizational affiliation, such as department of medicine, materials research laboratory, or social sciences institute.

Item 3f. Major Subdivision

Indicate your school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, or public health. *If there is no such subdivision, enter "None*."

Item 3g. Telephone and Fax Numbers

Provide a daytime telephone number and, if available, a fax number.

Item 4. Human Subjects

No Human Subjects. Check "No" if activities involving human subjects are not planned at any time during the *proposed* project period. The remaining parts of Item 4 are then not applicable.

Human Subjects Involved. Check "Yes" if activities involving human subjects are planned at any time during the *proposed* project period, either at the applicant organization or at any other performance site or collaborating institution. "Yes" should be checked even if the research is exempt from regulations for the protection of human subjects.

Item 4a. Exemptions from Human Subjects Regulations

Check "Yes" if the activities proposed are designated to be exempt from the regulations. Insert the exemption number(s) corresponding to one or more of the six Exemption Categories listed under "Exempt Human Subjects Research." If the proposed research corresponds to one or more of the exempt categories then the remaining parts of Item 4 of the Face Page are not applicable.

Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research may result in delays in the review of an application or the return of the application without review. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. In doubtful cases, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their website http://ohrp.osophs.dhhs.gov/ for guidance and further information.

Human Subjects Activities Not Exempt from Regulations. Check "No" if the planned activities involving human subjects are not exempt, and complete the remaining parts of Item 4.

Item 4b. Human Subjects Assurance Number

If the applicant organization has an approved Federal Wide Assurance (FWA), Multiple Project Assurance (MPA), Single Project Assurance (SPA) Number or Cooperative Project Assurance Number on file with the OHRP (http://ohrp.osophs.dhhs.gov/) that covers the specific activity, insert the number in the space provided.

Insert "None" in Item 4b if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature on the Face Page, is declaring that it will comply with 45 CFR 46 and proceed to obtain a human subject assurance (see http://ohrp.osophs.dhhs.gov). *Do not insert the human subjects assurance number of any collaborating institution in the space provided*.

NIH no longer requires IRB approval and certification of the proposed research prior to NIH peer review of an application (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html). As part of the peer review process, the peer review group carefully considers protections from research risk. The peer review group will assess the adequacy of safeguards of the rights and welfare of research participants based on the information in the application. See Item e. Human Subjects Research under "Content of Research Plan" in Section IV.D.

Item 4c. NIH-Defined Phase III Clinical Trial

Check "Yes" or "No" to indicate whether the project is an NIH-Defined Phase III clinical trial.

For the purpose of the Guidelines, an NIH-defined Phase III "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Item 5. Vertebrate Animals

Check "No" if activities involving vertebrate animals are not planned at any time during the proposed project period. The remaining parts of Item 5 are then not applicable.

Check "Yes" if activities involving vertebrate animals are planned at any time during this *proposed* project period, either at the applicant organization or at any other performance site or collaborating institution.

Item 5a. IACUC Approval Date

If the applicant organization has a full Animal Welfare Assurance of Compliance on file with the Office of Laboratory Animal Welfare (OLAW), enter the date of IACUC approval in the space provided.

While you do not need to enter an IACUC date, you still MUST complete section f. Vertebrate Animals of the Research Plan even though the animal activity is to take place at another institution. If you are selected for an award, NIH staff will inform you of the necessary steps for obtaining an appropriate Assurance/IACUC documentation.

Item 5b. Animal Welfare Assurance

If the applicant organization has a full Animal Welfare Assurance of Compliance on file with the Office of Laboratory Animal Welfare (OLAW), enter the Assurance number of the applicant organization in Item 5b. (To determine if your organization holds an Animal Welfare Assurance, see http://grants.nih.gov/grants/olaw/olaw.htm#assur.)

Insert "None" in Item 5b *if the applicant organization does not have an approved Animal Welfare Assurance* on file with OLAW. *Do not insert the Animal Welfare Assurance of any collaborating institution in the space provided*. By inserting "None" and, by the signing on the Face Page, the applicant organization is declaring that it will comply with PHS policy regarding the care and use of animals by establishing an IACUC and submitting an Animal Welfare Assurance and certification of IACUC approval when requested to do so by OLAW.

Small business organizations will typically fall into one of three (3) categories:

(1) The small business concern does not have and never plans to establish its own animal facilities but will always rely on the programs and facilities of larger organizations and universities. In this scenario, always enter "None" where the Assurance

number is required and complete the Vertebrate Animals section of the Research Plan.

(2) The small business concern has animal programs and facilities of their own *and* has a full Animal Welfare Assurance of Compliance on file with OLAW. Ordinarily, IACUC approval is valid for three years from the time of IACUC review. In this scenario, indicate your Assurance Number and IACUC approval date on the Face Page or you may provide IACUC approval in a "just-in-time" fashion prior to award. You *MUST* complete the Vertebrate Animals section of the Research Plan.

(3) The small business concern is in the process of establishing programs and facilities of their own for animals use *but does not* have an Assurance yet. In this scenario, insert "NONE" where the Assurance Number is required on the Face Page and insert "Pending" for the IACUC date. You *MUST* complete the Vertebrate Animals section of the Research Plan. The applicant organization remains responsible for submission of the follow-up IACUC verification whether that verification is submitted to the SRA prior to peer review or to the NIH or other PHS agency funding component prior to award.

Item 6. Dates of Proposed Period of Support

Routinely, SBIR and STTR Phase II awards do not exceed two years. Under special circumstances, applicants to NIH may propose longer periods of time for completion of the research project (e.g., feasibility demonstration). Such requests that deviate from the guidelines must be thoroughly justified.

The above applies to NIH ONLY, as CDC and FDA do not make awards for periods longer than the stated guidelines.

To select an appropriate beginning date for a *new* application, consult the following schedule:

SBIR AND STTR RECEIPT DATES PHASE I AND PHASE II	ESTIMATED AWARD DATE
April 1	November 1
August 1	March 1
December 1	July 1

Item 7. Costs Requested for Initial Budget Period

Item 7a. Direct Costs Requested for Initial Budget Period

Do *not* include amount requested for fee/profit. Enter the "Total Direct Costs for Initial Budget Period" from Form Page 4.

Item 7b. Total Costs Requested for Initial Budget Period

Enter the *sum* of (a) the "Total Direct Costs for Initial Budget Period" from Form Page 4, (b) the requested Fee on Form Page 4, and (c) the F&A/indirect costs (from the Checklist Form Page).

Item 8. Costs Requested for Entire Proposed Period of Support

Item 8a. Direct Costs Requested for Entire Proposed Period of Support

Enter the "Total Direct Costs for *Entire* Project Period" from Form Page 5.

Item 8b. Total Costs Requested for Entire Proposed Period of Support

Enter the *sum* of (a) the "Total Direct Costs for *Entire* Project Period" from Form Page 5, (b) the requested "Total Fee for Entire Proposed Project Period" on Form Page 5, and (c) the F&A/indirect costs (from the Checklist Form Page).

Item 9. Applicant Organization

Name the small business concern that will be legally and financially responsible for the conduct of activities supported by the award. *The small business concern is ALWAYS the applicant organization for an SBIR or STTR award*.

Enter the NIH-assigned Institutional Profile File (IPF) number.

Item 10. Type of Organization

Check "Small Business" under "For Profit." Check the boxes designating the small business as "woman-owned" or "socially and economically disadvantaged," if appropriate. (See Section III. Definitions.)

Small Business Certification. The applicant organization must certify that it will qualify as a small business concern at the time of award. The capture of information on socially and economically disadvantaged small business concerns and

women-owned small business concerns is strictly for statistical purposes (as requested by the Small Business Administration).

Item 11. Entity Identification Number, DUNS Number, Congressional District

Enter the 12-digit Entity Identification Number (EIN) assigned to the applicant organization by the Department of Health and Human Services Payment Management System for payment and accounting purposes. *DO NOT ENTER YOUR SOCIAL SECURITY NUMBER* as it is not appropriate for this item. Enter a Dun & Bradstreet (DUNS) number if the 9-digit identification code is available. Enter the number of the Congressional District.

Item 12. Administrative Official to Be Notified If Award Is Made

Name the small business applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and email address for the administrative official.

Item 13. Official Signing for Applicant Organization

Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. For electronic mail, enter the appropriate email address.

Item 14. Principal Investigator/Program Director Assurance

An original signature, in ink, is required. "Per" or "For" signatures are not acceptable. Date of signature must be included.

Item 15. Applicant Organization Certification and Acceptance

An original signature, in ink, is required. "Per" or "For" signatures are not acceptable. Date of signature must be included. *In signing the application Face Page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application*. The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant supported project or activities resulting from this application. The grantee organization may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Assurances/Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Definitions are provided in the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/policy.htm) and in Section X Assurances, Certifications and Other Policy Issues of this solicitation.

Human Subjects
Research on Transplantation of Human Fetal Tissue
Women and Minority Inclusion Policy
Inclusion of Children Policy
Research Using Human Embryonic Stem Cells
Vertebrate Animals
Debarment and Suspension
Drug-Free Workplace
Lobbying
Non-Delinquency on Federal Debt
Research Misconduct
Civil Rights
Handicapped Individuals
Sex Discrimination
Age Discrimination
Recombinant DNA and Human Gene Transfer Research
Financial Conflict of Interest
Certification of Research Institution Participation (*STTR only*)

In addition, SBIR/STTR applicants certify by the signature of the Official Signing for the Applicant Organization on the Face Page of the application that it is a small business concern, and if so indicated, is a woman-owned/socially and economically disadvantaged small business concern, and meets the definition(s) as stated in the

program announcement or that it will meet that definition at the time of award.

2. DESCRIPTION, PERFORMANCE SITES, AND KEY PERSONNEL FORM PAGE 2 (RTF | PDF)

Description (Abstract of Research Plan)

State the application's broad, long-term objectives and specific aims, referring to the health relatedness of the project. In addition, *discuss the potential of the research for technological innovation and commercial applications*. Describe concisely the research design and methods for achieving these goals.

Avoid summaries of accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. *Therefore, do not include proprietary/confidential information. DO NOT EXCEED THE SPACE PROVIDED*.

Performance Sites

Indicate where the work described in the Research Plan will be conducted. *One of the sites indicated must be that of the applicant small business concern*. If there is more than one performance site, list all the sites and provide an explanation on the Resources Format Page of the application.

State if a consortium/contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan. If a performance site is participating in research using human subjects, it is the responsibility of the applicant organization to assure that the performance site complies with the regulations in 45 CFR Part 46.

The research or research & development (R/R&D) project activity must be performed in its entirety in the United States. In those rare circumstances that necessitate that a portion of the research or R/R&D work be performed or obtained in a country outside of the United States because of the study design (e.g., patient populations), investigators must thoroughly justify the use of these sites in the application. Similarly, in those rare circumstances that necessitate the purchase of materials from other countries, investigators must thoroughly justify the request. These rare and unique situations will be considered on a case-by-case basis, and they should be discussed with NIH staff prior to submission of the application. Approval by the funding officer for such specific condition(s) must be in writing prior to issuance of an award.

Key Personnel

Key personnel are defined as all individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. *Consultants should also be included if they meet the definition of "key personnel*."

Start with the Principal Investigator. List the PI, last name first. Then list all other key personnel in alphabetical order, last name first. For each individual provide: name, organization (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project. Use additional pages as necessary.

Disclosure Permission Statement

Check "*Yes*" or "*No*" in response to the following question: *If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaboration, investment)?*

3. RESEARCH GRANT TABLE OF CONTENTS FORM PAGE 3 (RTF | PDF)

Provide the page number for each category listed on the Table of Contents. Consecutively number pages throughout the application. Place page numbers at the bottom of each page. Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

Identification of Proprietary Information. You are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the

Guidance on Preparation of SBIR and STTR Budgets

	MODULAR BUDGET FORMAT PAGE	FORM PAGE 4	FORM PAGE 5	STTR RESEARCH INSTITUTION BUDGET FORM PAGE	STTR RESEARCH INSTITUTION CERTIFICATION PAGE
SBIR Budget					
Small Business		X	X		N/A
Subcontracts		X	X		N/A
STTR Budget					
Small Business		X	X		N/A
Research Institution			X (future yrs.)	X (initial yr.)	N/A
Other Subcontracts		X	X		N/A

application contains information that constitutes trade secrets, information that is commercial or financial, or information that is confidential or privileged, *include a legend on Form Page 3 to identify the appropriate page numbers. Also identify the information by asterisks (*) and page number in the Research Plan*. For additional information concerning the inclusion of proprietary information, see Section VII. E. Innovations, Inventions and Patents.

4. BUDGET INSTRUCTIONS

Total Costs. Routinely, total costs for the entire proposed Phase II period do not exceed $750,000 for SBIR and STTR projects. However, under special circumstances, applicants may propose greater amounts of funds necessary and appropriate for completion of the project.

The ability to deviate from the statutory guidelines applies to NIH ONLY— Phase II applications to CDC and FDA are limited to $750,000 (total of direct, F&A/indirect and fee).

Contractual/Constultant Costs. The total amount of contractual costs and consultant fees normally may not exceed 50% of the total costs requested on a Phase II SBIR project. Contractual arrangements for scientific or technical services (e.g., laboratory testing of biological materials, clinical services) may involve costs such as personnel, supplies, and any other allowable expenses, including indirect costs.

STTR projects require that the single partnering research institution perform at least 30% of the R/R&D. Costs pertaining to the portion of the project to be conducted by the research institution are contractual costs to the small business concern.

Guidance on Preparation of SBIR and STTR Budgets. Above is a table summarizing the necessary budget forms for both modular and non-modular applications. Use this chart to ensure that you have submitted the correct forms appropriate to your specific type of application.

5. BUDGET INSTRUCTIONS

Budget for Initial Budget Period Form Page 4 (RTF | PDF)

Budget for Entire Proposed Period of Support, Form Page 5 (RTF | PDF)

The following instructions for preparing the budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" are applicable to all SBIR/STTR Phase II applications.

Detailed categorical budget information is to be submitted with the application.

- Submit Form Page 4 and Form Page 5, and follow the specific non-modular instructions for SBIR or STTR, as applicable.
- Form Page 4 reflects the total direct costs, which include the total costs of any contractual costs, requested for the initial (first 12 months) Phase II budget period. (F&A/indirect costs are requested

on the Checklist Page.) Form Page 4 also reflects the fee/profit requested.

- Form Page 5 reflects the total direct costs plus fee for the entire project period. This form is also used to prepare the *narrative budget justification*.
- Do not include any items that are treated by the applicant organization as indirect costs according to a Federal rate negotiation agreement, except for those indirect costs included in consortium/contractual costs.
- Submit a *separate* detailed budget (Form Page 4) for each participating consortium/contractual organization. For each, label that page accordingly. If consortium activity exceeds one year, also include a *separate* Form Page 5. See Consortium/Contractual Costs for specific instructions.
- Refer to the SBIR or STTR Reminder Sheet before submitting the grant application.

F&A/Indirect Costs are to be shown on the Checklist Page. The TOTAL costs (sum of direct, F&A and fee) are to be shown on the Face Page in Items 7b and 8b.

Phase II SBIR Budget

SBIR Initial Budget Period (Form Page 4)

The following items pertain individually to the completion of Form Page 4 (Detailed Budget for Initial Budget Period – Direct Costs Only), to be completed by the small business concern.

Personnel

Name. Starting with the Principal Investigator, list the names of *all* applicant organization employees who are to be involved on the project during the initial budget period, regardless of *whether a salary is requested*.

Role on Project. Identify the role (for example, Principal Investigator or statistician) of each individual listed on the project. *Describe their specific functions under Justification on Form Page 5*. The concept of Co-Principal Investigator is not recognized.

Type of Employment. List the number of months per year reflected in an individual's employment agreement with the organization. If employment is less than full time (e.g., 1/2 time or 3/4 time), enter an asterisk (*) after the number of months and *provide a full explanation under Budget Justification on Form Page 5*.

Percent Effort on Project. List the percentage of each individual's employment at the organization to be spent on *this project*. If an individual engages in other corporate responsibilities, such as management, the total percentage devoted to all research activities by the individual must be less than 100%. While a minimum percent effort is not stipulated for the PI on an SBIR project, note that the PI is the individual who is responsible for the scientific or technical aspects of the grant and for day-to-day management of the project.

Institutional Base Salary. The institutional base salary is defined as the annual compensation that the organization pays for the individual's employment, whether that individual's time is spent on research, administration, or other activities. Base salary excludes any income the individual may be permitted to earn outside of duties to the organization. Base salary may not be increased as a result of replacing corporate salary funds with grant funds.

Dollar Amount Requested

Salary Requested. Enter the dollar amounts for each position for which funds are requested. Calculate the totals for each position and enter the subtotals in each column where indicated. The maximum salary that may be requested is calculated by multiplying the individual's institutional base salary, defined above, by the percent of effort on this project. Congress has imposed and may continue to impose salary caps. Effective January 1, 2003, the salary limitation (cap) is $171,900. (See *NIH Guide for Grants and Contracts* and search on "salary limitation" or "salary cap.") *Organizations should request appropriate salary support without regard to Congressional salary caps. Any amount requested for salary that may be in excess of a salary cap will be adjusted at the time an award is issued*.

Fringe Benefits. Leave this column blank as *commercial (for-profit) organizations usually treat "fringe benefits" as indirect costs*. In certain cases, fringe benefits may be requested as a direct cost to the extent that they are treated consistently by the organization as a direct cost to all sponsors.

Totals. Calculate the totals for each position and enter the subtotals in each column where indicated.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of any consultants, *other than those involved in consortium/contractual arrangements*, who have agreed to serve in that capacity. Include consultant physicians in connection with patient care and persons who serve on external monitoring boards or advisory committees to the project.

Justify the request on Form Page 5. Briefly describe/justify the services to be performed, including the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Reminder: Letters of commitment from collaborators and consultants must be submitted with the application.

Equipment

Provide the total dollar amount requested. *List each item* of equipment separately. *Justify the request on Form Page 5*. Explain the need for any item that appears to be duplicated or equivalent to those listed in the "Resources" portion on these forms.

Supplies

Provide the total dollar amount requested. *Justify the request on Form Page 5*. Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. (Categories in amounts less than $1,000 do not have to be itemized.) If animals are to be purchased, state the species, the number to be used, their unit purchase cost, and their unit care cost.

Travel

Provide the total dollar amount requested. *Justify the request on Form Page 5*. Describe the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that agency policy requires that less than first-class air travel be used. Travel of a reasonable amount ($1,500-$2,000) may be proposed to attend conferences and similar meetings in the scientific field(s) of endeavor, to learn of new or emerging scientific interests of the PHS awarding components (for example, bioengineering), and to improve post award management. Travel to a scientific meeting in a foreign country is allowable, but this request should be thoroughly justified regardless of the dollar amount requested.

Patient Care Costs

The applicant organization may be reimbursed for inpatient and outpatient charges incurred incidentally to the proposed research. *Justify the request on Form Page 5*. Patient care costs do not include travel, lodging, and subsistence; request these costs in the "Other Expenses" category. Request consultant physician fees in the "Consultant Costs" category.

If inpatient and/or outpatient costs are requested, provide the names of any hospitals and/or clinics and the amounts requested for each on Form Page 5.

State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, the PHS awarding component can approve a provisional rate. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of other support for patient care costs, e.g., third-party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers. *Justify the request on Form Page 5*.

Other Expenses

Provide the total dollar amount requested. Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission in lieu of salary. *Justify costs on Form Page 5*.

Consortium/Contractual Costs

On the applicant organization's budget, list the *sum of all* consortium/contractual costs (separate lines provided for direct costs and F&A). *Justify the request on Form Page 5*.

Each participating consortium/contractual organization must submit a separate detailed budget for both the "Initial Budget Period (up to 12 months)" (Form Page 4) and, if the project period exceeds one year, for the "Entire Proposed Project Period" (Form Page 5). *Type the name of the consortium/ subcontractor at the top of these pages* to distinguish them from the small business concern, and number the pages sequentially. (Do not use 5a, 5b, 5c, etc.) Insert these additional page(s) after the applicant small business organization's budget pages.

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administrative (F&A) costs. Contractual arrangements for scientific or technical support services (e.g., laboratory testing of biological materials, clinical services, or data processing) may involve costs such as personnel, supplies, and any other allowable expenses, including indirect costs. Such contracts may be of sufficient scope to warrant a similar categorical breakdown of costs.

When F&A/indirect costs are requested by a consortium organization, enter these costs in the F&A cost category for each supplementary budget. Provide the F&A cost base and rate. Leave the direct cost category (above the F&A line) blank.

Fee

Enter the request for profit/fee as a *separate line item* below the "Total Direct Costs for Initial Budget Period." *Justify the request on Form Page 5*. A reasonable fee, not to exceed *7% of total costs* (direct and indirect) for each Phase (I and II) of the project, is available to small business concerns receiving awards under the SBIR/STTR program. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work.

The fee is not a direct or indirect "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee applies solely to the small business concern receiving the award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

Total Direct Costs for Initial Budget Period

Enter total direct costs for the Initial Budget Period (up to 12 months). Also enter this number in *Item 7a* of the Face Page.

SBIR Entire Proposed Period of Support (Form Page 5)

On Form Page 5, enter in the first column the budget category totals of the "Initial Budget Period" costs from Form Page 4.

Enter the totals under each budget category for all additional years of support requested. Identify with an asterisk (*), and justify any significant increases or decreases from the initial year budget, if applicable. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support. *Provide necessary justifications for the amount requested for profit/fee and other items described on the form*. Use continuation pages as necessary.

Enter in *Item 8a* on the Face Page, the amount for "Total Direct Costs for Entire Proposed Project Period" as indicated on Form Page 5.

Enter in *Item 8b* on the Face Page, "Total Costs Requested for Proposed Period of Support" the *sum* of the following amounts: (1) Item 8a, plus (2) Total profit/fee for Entire Proposed Project Period, plus (3) Total F&A costs as indicated on the Checklist Form Page.

SBIR applicants may proceed directly to the next section, Biographical Sketch.

Phase II STTR Budget

STTR Research Institution Budget Form Page (RTF | PDF)

Submit Form Page 4 and Form Page 5, which are to be completed by the applicant small business concern, *and* submit the STTR Research Institution Budget Form Page, which is to be *completed by the single partnering research institution (RI)*, in accordance with the instructions below.

The STTR Research Institution Budget Form Page identifies costs pertaining to the portion of the work to be performed by the research institution for the *initial (up to 12 months)* STTR Phase II project. The

research institution must also use a *separate* Form Page 5 to identify its costs for future years.

Reminder. The single partnering research institution must certify *at the time of application* that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution." Space has been provided on the form for the requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution upon signing the budget page.

STTR Initial Budget Period

Research Institution Budget Page. On the Research Institution's Budget Page, provide information for Personnel, Consultant Costs, Equipment, Supplies, Travel, Patient Care Costs, Other Expenses, Total Direct Costs, Facilities and Administrative (F&A) Costs, and Total Costs associated with the research institution's portion of the budget in the same manner as described above under "Phase II SBIR Budget." Provide the F&A cost base and rate. Also indicate the total direct costs and F&A costs in the field labeled "Consortium/Contractual Costs" on the Small Business Concern's Budget Page (Form Page 4). When the research institution requests F&A costs, these *costs are included as a direct cost for the Small Business Concern*.

Other Consortia/Subcontracts. Costs pertaining to arrangements for a portion of the project to be conducted by *other than* the "research institution" should be identified completing a *separate* Form Page 4 (and Form Page 5 if the budget exceeds one year) and completing it in the same manner as described above. *Justify costs pertaining to the research institution* under "Justification" on the *Small Business Concern's Form Page 5*. Total costs of the portion of the project to be performed by the research institution are also to be shown in the Justification section of Form Page 5. If space is not available on the form, attach continuation page(s) for this purpose.

STTR Entire Proposed Project Period Form Page 5 (RTF | PDF)

If the STTR project exceeds one year, use a *separate* Form Page 5 to identify costs pertaining to the portion of the project to be conducted by the research institution for the "Entire Proposed Project Period." *Identify the research institution's budget page by typing "Budget of Research Institution" at the top of Form Page 5*. Insert these additional pages *after* the budget pages of the small business concern (Form Page 4 and Form Page 5), numbering them sequentially. (Do not use 5a, 5b, 5c, etc.) Provide information for Personnel, Consultant Costs, Equipment, Supplies, Travel, Patient Care Costs, Other Expenses, Subtotal Direct Costs, Total Direct Costs, and Consortium/ Contractual Costs associated with the research institution's portion of the budget in the same manner as described above.

6. BIOGRAPHICAL SKETCH

Biographical Sketch Format Page (RTF | PDF)

Follow the format of the "Biographical Sketch Format Page" to prepare this section for *ALL* (modular *and* non-modular) grant applications. This section must contain the biographical sketches of *all KEY* personnel, *including consultants,* following the order as listed on Form Page 2. *A sample biographical sketch is available at* http://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf.

Each Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two pages of the four-page limit.

Complete the educational block at the top of the format page, and complete sections A, B, and C.

A. ***Positions and Honors.*** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. ***Selected Peer-Reviewed Publications or Manuscripts in Press (in chronological order).*** Do not include manuscripts submitted or in preparation.

C. ***Research Support.*** List both selected ongoing and completed (during the last three years) research projects (federal or non-federal support). *Begin with the projects that are most relevant to the research proposed in this application*. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. *Do not include percent of effort or direct costs*.

This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

Information on other support *beyond* that required in the biographical sketch should NOT be submitted with the application. For additional information and policy, see Section X, Other Support Policy.

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. It is used by reviewers for the "investigator" review criterion. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you *after* peer review. This information will be used to check that the proposed research has not already been Federally-funded.

7. RESOURCES

Resources Format Page (RTF | PDF)

Follow the instructions and format on the "Resources Format Page." *One of the sites indicated must be that of the applicant small business concern*. If there are multiple performance sites, then resources available at each site should be described.

All performance sites identified on Form Page 2 of the application should be described under "Facilities." Use continuation pages, if necessary.

The research to be performed by the applicant small business concern and its collaborators must be in U.S. facilities that are *available to and under the control of each party* for the conduct of each party's portion of the proposed project.

8. RESEARCH PLAN

No Specific Form Page
Use Continuation Page (RTF | PDF)

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). A suggested format for preparing this section is provided below. Be specific and informative, and avoid redundancies.

Introduction
(revised or supplemental applications only)

All revised and supplemental applications must include an Introduction. Do not exceed *three pages*. The "Introduction" is excluded from the page limitations of the Phase II application.

Insert the Introduction at the very beginning of the Research Plan. In the "Introduction," summarize any substantial additions, deletions, and changes that have been made. Include responses to criticisms in the previous summary statement. Identify these changes within the text of the Research Plan by appropriate bracketing, indenting, or changing of typography. Do not shade changes. Incorporate any work done since the prior version was submitted. A revised application will be returned if substantial revisions are not clearly apparent. Acceptance of a revised application automatically withdraws the prior version.

The introduction to a supplemental application should provide an overall description of the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Any budgetary changes for the remainder of the project period of the current grant should be discussed under the budget justification. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application. *Reminder: applications for competitive supplements must be discussed with NIH program staff prior to submission*.

Content of Research Plan

***Items a-d* of the Phase II Research Plan are limited to 25 pages, including all tables and figures.**

Organize *Items a-d* to answer these questions: (1) What do you intend to do? (2) What are the anticipated commercial products, processes, services and societal benefits? Why is the work important? (3) What has already been done? (4) How are you going to do the work?

The suggested format for the Research Plan (see page limitations above) is as follows:

Item a. Specific Aims

State the specific objectives of the Phase II research and development effort. State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product to ultimately be developed. You are encouraged to include milestones for each of the aims as these will be used in the evaluation process. *One page is recommended*.

Item b. Significance and Related R&D

Provide a clear statement of the specific technical problem or opportunity. Describe significant R/R&D that is directly related to the proposal including any conducted by the Project Manager/Principal Investigator or by the proposing small business concern. Describe how it relates to the proposed effort, and any planned coordination with outside sources. You must persuade reviewers of your awareness of key, recent R/R&D conducted by others in the specific topic area.

Briefly sketch the background to the present grant application, critically evaluate existing knowledge, and specifically identify the commercial opportunities and societal benefits that the project is intended to address. State the anticipated outcomes of the proposed Phase II approach if the project (Phase I and II) is successful. *Three to four pages for Item b are recommended*.

Item c. Preliminary Studies/Phase I Final Report

Among several criteria, a Phase II application will be reviewed based on the degree to which progress toward the Phase I objectives were met and feasibility demonstrated.

Phase I Final Report. A Phase I Final Report is required for all Phase II applications. There is no form page for the Phase I Final Report. It may be typed on plain white paper (or you may use the PHS 398 Continuation Page). *The recommended length for the narrative portion is 10 pages*. The report should be a presentation of the accomplishments of the Phase I effort. Abbreviations and language that may not be generally known to the broader scientific community should be avoided unless clearly defined.

The format for the Phase I Final Report is as follows:

1. State the beginning and ending dates for the period covered by the SBIR/STTR Phase I grant.
2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.
3. Summarize the specific aims of the Phase I grant and provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims of Phase I since the project was initiated.
4. List the titles and complete references to publications, manuscripts *accepted* for publication, patents, invention reports, and other printed materials, if any, that have resulted from the Phase I effort. Submit five copies of such items, except patent and invention reports, as an *Appendix*.

Item d. Experimental/Research Design and Methods

Include a detailed description of the Phase II R/R&D plan. The plan should indicate what will be done, where it will be done, and how the R/R&D will be carried out. Phase II R/R&D should address the objectives and the questions cited in the Specific Aims section. The methods planned to achieve each objective or task should be discussed in detail.

Discuss in detail the experimental design, procedures and protocols to be used, and the means by which the data will be analyzed and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. *Discuss the criteria that will be used to determine that feasibility has been demonstrated*. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Item e. Human Subjects Research

If *Item 4 on the Face Page* of the application has been marked "*Yes*," it is very important that you follow the detailed instructions in this section. Be sure to also consult information under Section X. Assurances, Certifications and Other Policy Issues.

Applicants conducting research using human subjects are encouraged to read the information at the following websites: http://ohrp.osophs.dhhs.gov/info.htm and http://www-cdp.ims.nci.nih.gov/brochure.html.

The following human subject information applies even if you are obtaining specimens from collaborators or if you are subcontracting the human research to a university or another entity.

Although no specific page limitation applies to the human subjects section of the application, be succinct.

Information under the *following headings MUST be included* in this portion of the Research Plan:

PROTECTION OF HUMAN SUBJECTS

INCLUSION OF WOMEN

INCLUSION OF MINORITIES

INCLUSION OF CHILDREN

DATA AND SAFETY MONITORING

Applications that fail to comply with this requirement will be designated as incomplete and will constitute grounds for the PHS to return the application without peer review.

In conducting peer review, Scientific Review Groups (SRGs) will evaluate proposed plans for inclusion of minorities and members of both sexes/genders, plans for sex/gender and racial/ethnic subgroup analyses of NIH defined Phase III clinical trials, plans for recruitment/outreach and retention in the design of clinical trials, and any justifications for exclusion of a sex/gender or racial/ethnic subgroup.

This evaluation will be a part of the Approach criterion (see SBIR/STTR Review Criteria). The evaluation of the inclusion plans will be factored into the overall score that the SRGs award for scientific and technical merit of the application. In addition, awards will not be made if the research project does not comply with this policy.

In the *Human Subjects Research section*, applicants must (1) address the involvement of human subjects and protections from research risk relating to their participation in the proposed Research Plan (see Non-Exempt Human Subjects Research for specific requirements), or (2) provide a justification for exemption with sufficient information about the involvement of the human subjects to allow a determination by peer reviewers and NIH staff that a claimed exemption is appropriate (see Exempt Human Subjects Research for specific requirements). The table below is intended to provide guidance on what must be addressed in the Human Subjects Research section.

Non-Exempt Human Subjects Research

PROTECTION OF HUMAN SUBJECTS

If you marked "Yes" for Item 4 on the Face Page of the application and did not claim any exemptions from the regulations, create a section entitled "*Protection of Human Subjects*." In this section, you must provide information to *address all four evaluation criteria below* as they apply to the research you are proposing.

Failure to address the following human subjects protection criteria will result in the application being designated as incomplete, and it will be returned without peer review.

Under each criterion, indicate whether the information relates to the primary research site, to a collaborating performance site(s), or to all sites.

1. ***Risks to the Subjects***

   a. *Human Subjects Involvement and Characteristics*. Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

   b. *Sources of Materials*. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

   c. *Potential Risks*. Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

Guidance for Preparing the Human Subjects Research Section

SCENARIO	HUMAN SUBJECTS	EXEMPT	CLINICAL RESEARCH	CLINICAL TRIAL	REQUIREMENTS
A	No	N/A	N/A	N/A	– Indicate "No Human Subjects Research"
B	Yes	No	Yes	No	– Address Protection of Human Subjects – Address Inclusion of Women and Minorities in clinical research – Address Inclusion of Children – Ethnic/Racial "Targeted/Planned Enrollment Table Format Page" (New applications; Competing Continuation applications and Competing Supplements if new protocols) – Ethnic/Racial "Inclusion Enrollment Report Table Format Page" (Competing Continuations, Competing Supplements, and Annual Grant Progress Reports)
C	Yes	No	Yes	Yes	– All requirements in Scenario B – Data and Safety Monitoring Plan *Note: Phase III Trials require a Data and Safety Monitoring Board*
D	Yes	Yes	No	N/A	– Indicate Exemption Number – Justification that the designated exemption is appropriate – Address Inclusion of Women and Minorities – Address Inclusion of Children

2. ***Adequacy of Protection Against Risks***

   a. *Recruitment and Informed Consent*. Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document need not be submitted to the PHS unless requested.

   b. *Protection Against Risk*. Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve clinical trials (biomedical and behavioral intervention studies), describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

3. ***Potential Benefits of the Proposed Research to the Subjects and Others.*** Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. ***Importance of the Knowledge to Be Gained.*** Discuss the importance of the knowledge gained

or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the Principal Investigator must provide in this section of the application a list of the collaborating sites and their OHRP assurance numbers. Further, the Principal Investigator must obtain in writing, and keep on file, an assurance from each site that the four previous points have been addressed adequately at a level of attention that is at least as high as that documented at the applicant organization. Site(s) added after an award is made also must adhere to the above requirements.

Exempt Human Subjects Research

If you marked "Yes" for Item 4 on the Face Page and claimed an exemption from the human subjects regulations, then identify which one or more of the exemptions identified below is claimed. Provide a justification with sufficient information about the involvement of human subjects in the proposed research to allow a determination by peer reviewers and NIH staff that the designated exemption is appropriate.

Population Sample. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

Sources. Applicants should identify the sources of research material obtained from living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Even if the research you propose is exempt from these regulations, you MUST address the inclusion of women and members of minority groups and their subpopulations, and the inclusion of children in developing the research design (specific instructions follow).

Exemption Categories. The six categories of research that qualify for exemption from coverage by the regulations include activities in which the only involvement of human subjects will be in one or more of the following categories:

Exemption 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exemption 5: Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If the research you propose does not meet the requirements for exempt research, then it is not exempt from human subjects regulations and you must follow the instructions in the Non-Exempt Human Subjects Research section.

Some exemptions do not apply when research involves vulnerable populations as indicated in 45 CFR 46.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

If you are conducting clinical research (see definition in Section III), create a section heading entitled "*Inclusion of Women*" and a separate section heading entitled "*Inclusion of Minorities*." Place these sections immediately after the Human Subjects Research section in your application. Address each of the items identified below with respect to your plans for the "Inclusion of Women" and the "Inclusion of Minorities" as they relate to the proposed research. Although no specific page limitation applies to these sections of the application, be succinct.

Applications that fail to address the Inclusion of Women and Minorities as subjects in clinical research will result in the application being designated as incomplete, and it will be returned without peer review.

NIH policy requires that women and members of minority groups and their subpopulations be included in all NIH-supported biomedical and behavioral clinical research projects involving human subjects (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html).

The inclusion must be addressed in developing a research design appropriate to the scientific objectives of the study. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research. This policy applies to research subjects of all ages.

Information to Be Provided for All Clinical Research Studies

See definition of clinical research in Section III. Definitions. Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic group and provide a rationale for selection of such subjects in terms of the scientific objectives and proposed study design. The description may include (but is not limited to) information on the population characteristics of the disease or condition under study, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned study.

This section of the Research Plan must include the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design.
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- The proposed dates of enrollment (beginning and end).

- A description of proposed outreach programs for recruiting women and minorities in clinical research as subjects.

- The proposed sample composition using the "5/01 Targeted/Planned Enrollment Format Page" and/or the "5/01 Inclusion Enrollment Report Format Page." (Specific instructions follow the ethnic/racial category descriptions.)

The Office of Management and Budget (OMB) Standards for Collecting and Reporting Data on Race and Ethnicity

(www.whitehouse.gov/OMB/fedreg/ombdir15.html) OMB Directive No. 15 defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting (including NIH). The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. The standards were revised in 1997 and now include two ethnic categories, "Hispanic or Latino" and "Not Hispanic or Latino." There are five racial categories: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White. Reports of data on race and ethnicity shall use these categories. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. The following definitions apply for the *ethnic* and *racial* categories (OMB Directive 15).

Ethnic Categories

- ***Hispanic or Latino.*** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

- ***Not Hispanic or Latino.***

Racial Categories

- ***American Indian or Alaska Native.*** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

- ***Asian.*** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (*Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies*.)

- ***Black or African American.*** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

- ***Native Hawaiian or Other Pacific Islander.*** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

- ***White.*** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Standards for Collecting Data. When an investigator is planning data collection items on ethnicity and race, categories identified above should be used. The collection of greater detail is encouraged. However, more detailed items should be designed in a way that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on ethnicity and race. When ethnicity and race are collected separately, ethnicity shall be collected first. Respondents shall be offered the option of selecting one or more racial designations. When data on ethnicity and race are collected separately, provision shall be made to report the number of respondents in each racial category who are Hispanic or Latino. When aggregate data are presented, the investigator shall provide the number of respondents who selected only one category, for each of the five racial categories. If data on multiple responses are collapsed, at a minimum the total number of respondents reporting "more than one race" shall be made available. Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

Additional Information to Be Provided for NIH-Defined Phase III Clinical Trials

This information applies when Item 4 (Human Subjects Research) *and* Item 4c (NIH-defined Phase III Clinical Trial) on the Face Page are marked "Yes."

If an *NIH-defined Phase III clinical trial* is proposed, the application must address whether the investigator expects to find clinically important sex/gender and/or race/ethnicity differences in the

intervention effect. See definition of clinical trial in Section III. Definitions. The discussion may include supporting evidence and/or data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies.

In conducting peer review for NIH-defined Phase III clinical trials, Scientific Review Groups (SRGs) will evaluate proposed plans for inclusion of women and minorities in clinical research and plans for sex/gender and racial/ethnic subgroup analyses, plans for recruitment/outreach and retention in the design of clinical trials, and any justifications for exclusion of a sex/gender or racial/ethnic subgroup. This evaluation will be a part of the Approach criterion (see description of review criteria in Section VI. B). The evaluation of the inclusion plans will be factored into the overall score that the SRGs assign for scientific and technical merit of the application. In addition, awards will not be made if the research project does not comply with this policy.

The Research Plan also must include *one* of the following plans:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups.
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged).
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Completing the Tables for Reporting Race and Ethnicity Data for Subjects in Clinical Research

New Applications

Use the *Targeted/Planned Enrollment Table Format Page* (RTF | PDF). Provide the study title and plans for the total number of subjects proposed for the study. Also provide the distribution by ethnic categories and by sex/gender according to the format in the Targeted/Planned Enrollment Table. If there is more than one study, provide a separate table for each study. List any proposed racial/ethnic subpopulations below the table. If the proposed research uses existing data, then applicants must use the formats for Competing Continuations, Competing Supplements and Annual Grant Progress Reports.

Competing Continuations, Competing Supplements and Annual Grant Progress Reports

For *Competing Continuations* involving the collection of *new/additional clinical data*, use the *Targeted/Planned Enrollment Table Format Page* (RTF | PDF) to estimate the distribution of subjects proposed for the study. Provide the study title and plans for the total (cumulative) number of subjects proposed for the study (total planned enrollment). Provide the distribution of subjects by ethnic and racial categories and by sex/gender according to the format in the 5/01 Targeted/Planned Enrollment Table. If there is more than one study, provide a separate table for each study.

For *Competing Continuations* that *do not* involve the collection of new/additional clinical data, and for *Competing Supplement Applications and Annual Grant Progress Reports,* use the *Inclusion Enrollment Report* (RTF | PDF).

For *Annual Grant Progress Reports*, if there are changes from the targeted/planned enrollment originally approved, a revised targeted/planned enrollment page and an inclusion enrollment report reflecting data collected to-date should be submitted.

The Inclusion Enrollment Report contains two parts: part A is for all subjects and part B is for Hispanics or Latinos. For Part A provide the distribution of subjects by ethnic and racial categories and by sex/gender according to the format in the 5/01 Enrollment Report Table. Part B should include information on the race of all Hispanics (or Latinos) enrolled in Part A. If there is more than one study, provide a separate table for each study. List any proposed ethnic/racial subpopulations as an attachment to the table. In filling out the 5/01 Inclusion Enrollment table, the investigator should not assume or guess a subject's ethnic or racial affiliation. The investigator should collect the data using instruments that, at a minimum, allow all

respondents to select their ethnic and racial affiliation separately. Under racial affiliation, subjects must be provided the option of selecting more than one race. When reporting these data to NIH, subjects who selected only one of the five racial categories should be designated in that category. Subjects who selected more than one racial category should be reported in the "More than one race" category. For previously funded studies that used an earlier NIH reporting format, the earlier reporting format is ***not*** directly transferable to the new format. Investigators should review the instructions and frequently asked questions about using the new format at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

INCLUSION OF CHILDREN

If you have marked "Yes" for Item 4 on the Face Page of the application, create a section heading entitled "*Inclusion of Children*." Place it immediately following the "Women and Minority Inclusion in Clinical Research" section of the application.

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH (see http://grants.nih.gov/grants/funding/children/children.htm for additional information), unless there are clear and compelling reasons not to include them. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion. (See NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects, http://grants.nih.gov/grants/guide/notice-files/not98-024.html.)

Applications that fail to address the Inclusion of Children will result in the application being designated as incomplete, and it will be returned without peer review.

In the section entitled "Inclusion of Children," provide either a description of the plans to include children or if children will be excluded from the research, the application or proposal must present an acceptable justification (see below) for the exclusion.

If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children.

When children are included, the plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Scientific Review Groups will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of children in the research project.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.
2. There are laws or regulations barring the inclusion of children in the research.
3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.
4. A separate, age-specific study in children is warranted and preferable. Examples include:
   a. The relative rarity of the condition in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
   b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
   c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children

in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions, to allow children to be included rather than excluding them; or

5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
6. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children); or
7. Other special cases justified by the investigator and found acceptable to the review group and the Institute Director.

DATA AND SAFETY MONITORING PLAN

If you have marked "*Yes*" for Item 4 on the Face Page of the application, *and* your proposed research includes a *clinical trial*, create a section heading entitled "*Data and Safety Monitoring Plan*." Place it immediately following the "Inclusion of Children" section.

NIH policy requires that investigators submit a general description of the Data and Safety Monitoring Plan for clinical trials (biomedical and behavioral intervention studies) as part of the research application. In developing your Data and Safety Monitoring Plan, you should refer to the *NIH Policy For Data and Safety Monitoring* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html. See also http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Applications that fail to include a Data and Safety Monitoring Plan will result in the application being designated as incomplete, and it will be returned without peer review.

A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for monitoring, and how Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with IND or IDE regulations. Although no specific page limitation applies to this section of the application, be succinct.

The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual/Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB – required)

NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for *multi-site* clinical trials involving interventions that entail potential risk to the participants, *and generally for Phase III clinical trials*. Although Phase I and Phase II clinical trials may also use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.

A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html).

Item f. Vertebrate Animals

If Item 5 on the FACE PAGE of the application has been marked "*Yes,*" you *must* address the following five points. *This information IS REQUIRED even if the animal studies will be performed by a collaborating organization*. Be sure to consult the information under Section X. Assurances, Certifications and Other Policy Issues, subsection F. Vertebrate Animals.

1. Provide a detailed description of the proposed use of the animals in the work previously outlined in the Experimental Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

2. Justify the use of animals, the choice of species, and the numbers used.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize discomfort, distress, pain and injury.
5. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present justification for not following the recommendations.

If the applicant small business concern does not have its own animal facilities and plans to utilize the facilities of a collaborating institution, such arrangements must be detailed in the application. *Both the applicant small business concern and the collaborating institution, as well as any other performer at a different performance site, must have OLAW-approved Animal Welfare Assurances on file before an award can be made*.

In accordance with the 2002 change in PHS Policy on Humane Care and Use of Laboratory Animals, the verification of IACUC approval may be submitted subsequent to peer review and at any time prior to award unless specifically required earlier by NIH or other PHS agencies. In no case may PHS agencies make an award (competing or non-competing) without verification of IACUC approval. Ordinarily, IACUC approval is for three years from the time of IACUC review.

Item g. Literature Cited

List literature citations. Each citation must include the title, names of all authors, the name of the book or journal, volume number, page numbers, and year of publication. Be judicious in compiling a relevant and current bibliography. It need not be exhaustive.

Item h. Contractual Arrangements

Explain the programmatic and fiscal arrangements made between the applicant small business concern and the contractor(s). The consortium investigator and the authorized official at the consortium institution(s) must provide a signed statement or confirming letters stating that "The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium grant policy (http://grants1.nih.gov/grants/policy/nihgps_2001/part_iib_6.htm#_Toc504812171) and are prepared to establish inter-institutional agreements consistent with that policy." Include confirming letters with the application. *These letters are required before an award can be made*.

Item i. Consultants

Involvement of consultants in the planning and research stages of the project is permitted. If such involvement is intended, it should be described in detail. Attach appropriate letters from each individual confirming his or her role in the project. Include biographical sketches for each consultant.

Item j. Commercialization Plan (formerly Product Development Plan [PDP])

All Phase II applications *and* Fast-Track applications must include a succinct Commercialization Plan, formerly referenced as a "Product Development Plan (PDP)." The Commercialization Plan is limited to *15 pages*. Be succinct. There is no requirement for applicants to use the maximum allowable pages allotted to the Commercialization Plan.

Create a section entitled, "Commercialization Plan," and provide a description in each of the following areas:

1. ***Value of the SBIR/STTR Project, Expected Outcomes, and Impact.*** Describe, in layperson's terms, the proposed project and its key technology objectives. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.
2. ***Company.*** Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current

products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

3. ***Market, Customer, and Competition.*** Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation.

   Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product.

   Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. *(It is very important that you understand and know the competition.)*

4. ***Intellectual Property (IP) Protection.*** Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

5. ***Finance Plan.*** Describe the necessary financing you will require, and when it will be required, as well as your plans to raise the requisite financing to launch your innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

   - Letter of commitment of funding.
   - Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
   - Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.
   - Specific steps you are going to take to secure Phase III funding.

6. ***Production and Marketing Plan.*** Describe how the production of your product/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/service. For example, explain plans for licensing, internet sales, etc.

7. ***Revenue Stream.*** Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

Applicants are *encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization* of the product(s) or service(s) resulting from the SBIR/STTR grant. *Place relevant letters following letters from consultants and collaborators*.

Your Phase III funding may be from any of a number of different sources including, but not limited to: SBIR/STTR firm itself; private investors or “angels”; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; State finance programs; non SBIR-funded R&D or production commitments from a Federal agency with the intention that the results will be used by the United States government; or other industrial firms.

Item k. Prior SBIR/STTR Phase II Awards

A small business concern that has received more than 15 Phase II SBIR/STTR awards during the preceding five (5) fiscal years must document the extent to which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR/STTR awards. If not applicable, this section of the Research Plan should indicate so.

If applicable, the following information must be submitted in the application regarding each such prior Phase II award: (1) name of awarding agency; (2) award number and date; (3) amount of award; (4) title of project; (5) source, date, and amount of Phase III funding agreement; and (6) commercialization status of each Phase II award.

Item I. Research Institution Certification

(*Applicable only to STTR*)

The single partnering research institution must certify *at the time of application* that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution." Space has been provided on the STTR Research Institution Budget Form Page or the modular STTR Research Institution Certification Format Page for the requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution upon signing the budget page.

Use "*STTR Research Institution Budget Page*" (RTF | PDF). See the instructions in Section IV, Phase II STTR Budget.

The signature of the duly authorized representative of the research institution on the "STTR Research Institution Budget Page" (non-modular applications) or the "STTR Research Institution Certification Page" (modular applications) certifies, among other things, that at least 30% of the work proposed on the Phase I or Phase II project will be performed by the partnering research institution.

Include the Research Institution Certification Format Page (or a letter containing the same information) at the end of the application following any letters from consultants.

The certification, with the signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution, must be included with the application or the application will be deemed incomplete and returned without peer review.

9. APPENDIX

Include *five collated sets* of all appendix material, in the same package with the application, following all copies of the application. Identify each item with the name of the Principal Investigator. *Do not intermingle appendix materials with the application*.

New, Revised, Competing Continuation, and Supplemental applications may include the following materials in the appendix:

- Up to 10 publications, manuscripts (*accepted* for publication), abstracts, patents, or other printed materials directly relevant to this project. These may be stapled as sets. *Manuscripts submitted for publication should not be included*.
- Surveys, questionnaires, data collection instruments, and clinical protocols. These may be stapled as sets.
- Original glossy photographs or color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 25-page limit of *Items a-d* of the Research Plan. No photographs or color images may be included in the appendix that are not also represented within the Research Plan.

Do not use the appendix to circumvent the page limitations of the Research Plan. Graphs, diagrams, tables, and charts that do not need to be in a glossy format to show detail must not be included in the appendix. An application that does not observe these limitations will be returned. These appendix limitations may not apply to specialized grant applications. Request and follow the additional instructions for those applications.

The appendix will not be duplicated with the application and will be sent only to certain members of the SRG who will serve as the primary reviewers of the application.

10. CHECKLIST

Checklist Form Page (RTF | PDF)

This is the next-to-last form page of the application, but is the last page to be numbered.

Request F&A/Indirect Costs in Section 3 on the Checklist Form Page.

Type of Application

Check all that apply.

Inventions and Patents

Check "No" if no inventions were conceived or reduced to practice during the course of work under this project. The remaining parts of the item are then not applicable.

Check "Yes" if any inventions were conceived or reduced to practice during the previous period of support. Also indicate whether this information has been previously reported to the PHS or to the

applicant organization official responsible for patent matters.

Program Income

NIH policy requires applicants for research grants to include in their grant applications an estimate of the amount and source of program income (defined below) expected to be generated as a result of the project for which funding is being sought. The specific policies that govern the treatment of program income under research grants are set forth in the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps/).

Program Income is defined as: gross income earned by a grant recipient during the budget period of the grant as a result of activities supported by the grant award. The *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps) contains a detailed explanation of program income, ways in which it may be generated and accounted for, and the various options for its use and disposition.

Examples of program income include:

- Patent or copyright royalties.
- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing.
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds.
- Third-party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity.
- Funds generated by the sale of products developed under the grant, which include but are not limited to drugs, assays, devices, instrumentation, software, laboratory techniques/methodologies, and testing/training devices or systems.
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals.

Generally, SBIR/STTR grantee organizations that earn program income may be authorized to have such income added to the grant account and used to further the objectives of the research project. Authorization must be requested from the Grants Management Officer of the appropriate PHS awarding component.

If *no program income* is anticipated during the period(s) for which grant support is requested, no other action is necessary.

If the *response to this item is "Yes,"* follow the prescribed format to reflect, by budget period, the amount and source(s) of anticipated program income. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income. *All program income earned during the budget period must also be identified on the Financial Status Report*.

The distribution of any income derived from royalties or licensing of an invention or patent is subject to specific provisions under 37 CFR Part 401. If any such income is anticipated, the applicant small business concern is encouraged to contact:

National Institutes of Health
Extramural Inventions and Technology Resources Branch
(301) 435-1986; Fax: (301) 480-0272
Email: gs60a@nih.gov or edison@od.nih.gov

Applicants with questions concerning any aspect of this topic are encouraged to contact the Grants Management Officer of the appropriate PHS awarding component or:

NIH, Division of Grants Policy
(301) 435-0949; Fax: (301) 435-3059.

Assurances/Certifications

Each application to the PHS requires that the following assurances and certifications listed on the Checklist be verified by the signature of the official signing for the applicant organization on the Face Page of the application. See Section X. Assurances, Certifications and Other Policy Issues.

Human Subjects
Research Using Human Embryonic Stem Cells
Research on Transplantation of Human Fetal Tissue
Women and Minority Inclusion Policy
Inclusion of Children Policy
Vertebrate Animals
Debarment and Suspension
Drug-Free Workplace
Lobbying
Non-Delinquent Federal Debt
Research Misconduct
Civil Rights

Handicapped Individuals
Sex Discrimination
Age Discrimination
Recombinant DNA and Human Gene Transfer Research
Financial Conflict of Interest
Certification of Research Institution Participation (*STTR Only*)

In addition, SBIR/STTR applicants certify by the signature of the Official Signing for the Applicant Organization on the Face Page of the application that it is a Small Business Concern, and if so indicated, is a woman-owned/socially and economically disadvantaged small business concern, and meets the definition(s) as stated in the program announcement or that it will meet that definition at the time of award.

Facilities and Administrative Costs

To request Facilities and Administrative (F&A) costs, complete Section 3 on the Checklist.

Facilities and Administrative (F&A) costs are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. These costs were previously referred to as "indirect costs," and, in most instances, will be referred to in this document as "F&A costs."

You are encouraged to visit the following Division of Financial Advisory Services (DFAS) websites or call the DFAS staff at 301-496-2444 for guidance:

Main DFAS website, http://ocm.od.nih.gov/dfas/dfas.htm

FAQS, http://ocm.od.nih.gov/dfas/faqindirectcosts.htm

Listing of unallowable and unallocable costs and the related FAR citation for each, http://ocm.od.nih.gov/dfas/unallowables.htm

If the applicant small business concern has a currently effective negotiated F&A cost rate with a Federal agency, it should be used when calculating proposed F&A costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services [HHS]. See "Negotiation of F&A Costs" later in this section.)

If applicable, indicate your organization's most recent F&A cost rate with DFAS or with another Federal agency. If your applicant organization is in the process of negotiating or renegotiating a rate, use that rate on the Checklist.

Commercial (for-profit) organizations usually treat "*fringe benefits*" as F&A costs. These fringe benefits are applied to direct salaries charged to projects either through a fringe benefit rate or as part of an overhead/F&A cost rate.

Generally, F&A cost rate structures for commercial organizations follow a single, two-rate (for example, fringe and overhead rates), or three-rate (for example, fringe, overhead, and General and Administrative expense rates) system. A Single Rate structure is illustrated at http://ocm.od.nih.gov/dfas/examples.htm.

If you do not have currently effective negotiated F&A cost rates with a Federal agency, then propose estimated actual F&A costs. If you are considered for an award, you will be asked to submit detailed documentation justifying the proposed rate if it exceeded 25% of the total direct costs.

1. Complete line 3a (Initial Budget Period) for first 12-month budget period, line 3b (-02 Year) for second budget period, and subsequent year(s) as appropriate.
2. Under "Explanation," insert "Rate to be negotiated with NIH" if you do not have a currently negotiated F&A cost rate with a Federal Agency. If you have a currently effective negotiated F&A cost rate with a Federal agency, it should be used when calculating proposed F&A costs.

If the requested F&A rate is 25 percent or less, F&A costs will be awarded at the requested rate.

However, applicant organizations are reminded that only actual F&A costs are to be charged to projects. If awarded at a rate of 25% or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate. *If the requested F&A rate is greater than 25 percent, additional information will be required prior to award to justify the requested rate*.

Negotiation of F&A Costs

The Division of Financial Advisory Services (DFAS), Office of Acquisition Management and Policy, NIH, is the office authorized to negotiate F&A cost rates with small business concerns receiving NIH SBIR/STTR awards. *Upon request of the NIH, the applicant small business concern should provide DFAS with an F&A cost proposal and supporting*

financial data for the most recently completed fiscal year. If financial data is not available for the most recently completed fiscal year, proposals showing estimated rates and support for same should be submitted.

The F&A cost proposal, based on company-wide cost data, should be accompanied by the following supporting information:

1. Profit and loss statement and balance sheet for the applicant organization's most recently completed fiscal year. Certified statements prepared by a CPA engaged to conduct an annual audit should be submitted, if available. The F&A cost proposal should include a reconciliation with the income statement; that is, there should be a cross-referencing from amounts on the income statement to amounts shown in the proposal, and a clear identification of individual elements (labor, materials, other expenses, etc.) of independent (self-sponsored) research and development (IR&D) expenses. IR&D costs are not allowable under NIH awards.
2. Listing of categories of costs normally classified and claimed as direct costs on Federal awards and non-Federally supported projects or activities.
3. Explanation of how the organization accounts for paid absences (vacation, holiday, and sick leave).
4. Certification of Final Indirect Costs as specified in FAR Part 52.242-4. This Certificate is to be completed by an official at a level no lower than a vice president or chief financial officer of the business segment submitting the proposal.

Smoke-Free Workplace

Does your organization currently provide a smoke-free workplace and/or promote the nonuse of tobacco products or have plans to do so? Check the appropriate box marked "Yes" or "No." Response to the question has no impact on the review or funding of this application.

11. PERSONAL DATA

Use the "Personal Data Form Page" (RTF | PDF). Follow the instructions on the form.

E. Market Research

The PHS will not support any market research under the SBIR/STTR programs. Neither will it support studies of the literature that will lead to a new or expanded statement of work. Literature searches where the commercial product is a database are acceptable.

For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the research project. It includes various types of research, such as the size of potential market and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a Research Plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

V. GRANT APPLICATION SUBMISSION REQUIREMENTS

The NIH's Center for Scientific Review (CSR) is the *single* receiving point for all NIH, CDC, and FDA SBIR/STTR grant applications. If your application is relevant to more than one awarding component, you need only submit the original application and five copies to CSR, and CSR will assign the application to all such components. Do not submit identical applications with requests for assignment to different funding components.

Cover Letters. You may include a cover letter with your application to: a) suggest assignment(s) to potential awarding component(s) (e.g., NIA, NIAMS, NINDS); b) indicate a specific area of expertise that should be represented on the study section committee and c) identify competitors who have direct conflicts of interest.

A. Receipt, Review and Award Dates

A grant application submitted under this SBIR/STTR Phase II Grant Solicitation will be considered on time if it is received by or mailed on or before the published receipt date and a proof of mailing is provided.

SBIR AND STTR RECEIPT DATES PHASE I AND II	AIDS AND AIDS-RELATED APPLICATIONS	NATIONAL TECHNICAL MERIT REVIEW	ADVISORY COUNCIL BOARD REVIEW	ESTIMATED AWARD DATE
April 1, 2003*	May 1, 2003	June/July	Sept/Oct	November
August 1, 2003	September 1, 2003	Oct/Nov	Jan/Feb	March
December 1, 2003*	January 2, 2004	Feb/March	May/June	July

* *Applications to the Centers for Disease Control and Prevention may be submitted only on the April 1 and December 1, 2003 receipt dates. CDC and FDA do not participate in the STTR program.*

Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark or a dated receipt from a commercial carrier or the U.S. Postal Service.

If the receipt date falls on a weekend, it will be extended to the following Monday. If the date falls on a holiday, it will be extended to the following workday. The application will be considered on time if it is received by or mailed on or before that day and a proof of mailing is provided.

The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter, addressed to the Division of Receipt and Referral, Center for Scientific Review, with the signed, completed application. No request for a waiver will be considered prior to receipt of the application.

SBIR/STTR applications in response to Request for Applications (RFAs) or Program Announcements (PAs) with other than standard (Apr 1, Aug 1, Dec 1) receipt dates must be received by the specified dates. These RFAs/PAs are issued separately through the *NIH Guide for Grants and Contracts*.

RECEIPT OF SBIR/STTR PHASE II APPLICATIONS

Phase II applications may be *submitted on any of the three published receipt dates*, either before or after expiration of the Phase I budget period. However, Phase II grant applications should be submitted *no later than the first six receipt dates following expiration of the Phase I budget period*.

Applicant small business concerns are reminded that Phase II funding is based on the results of Phase I, demonstration of feasibility, scientific and technical merit, and commercial potential of the Phase II application. *Applicants are cautioned that applications demonstrating insufficient results in Phase I may not receive a score in the peer review process (see* Section VI. Method of Evaluation and Selection Criteria*).*

B. Number of Copies

Original Plus 5 Copies

Submit the *original and five* exact, clear, single-sided photocopies of each application. The *original* must be signed by the Principal Investigator and a corporate official authorized to act for the applicant organization.

C. Bindings and Packaging

Do not bind or staple the six sets together, but secure each with rubber bands or paper clips.

DO NOT include more than one application set (original plus 5 copies) in each mailing envelope.

D. Mailing and/or Delivery Addresses

Mail or deliver the complete, signed, and typewritten original and five signed, exact, clear, single-sided photocopies of the application in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive
Room 1040-MSC 7710
Bethesda, MD 20892-7710
Phone: (301) 435-0715

Change zip code to 20817
for express mail or courier service

Until further notice, all applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the USPS. Applications delivered by individuals to the Center for Scientific Review will no longer be accepted. For additional information, see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html.

Attach to the bottom of the Face Page the appropriate SBIR or STTR label (RTF | PDF).

E. Assignment of Grant Applications

The Center for Scientific Review (CSR) will assign appropriately completed applications to the Scientific Review Groups (commonly referred to as "SRGs" or "study sections") that will perform the scientific/ technical merit review. The CSR website lists the recurring small business review panels. You may refer to the following link, http://www.csr.nih.gov/review/sba.asp, and suggest a specific group (e.g., ZRG1 SSS D 10B).

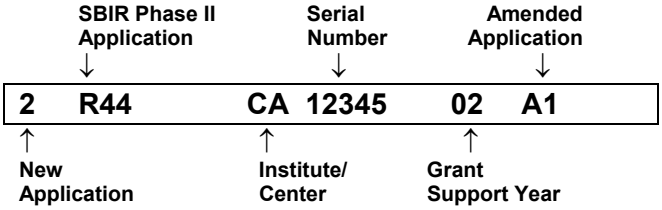
In addition, CSR will assign each application to the agency awarding component that is the potential funding component. When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign your application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in your application are designated as secondary assignees. If your application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this solicitation.

F. Notification of Receipt

Usually within six weeks after the receipt date, the CSR/NIH will send the Principal Investigator and the applicant organization a notification of receipt of the application. The notification will indicate a grant application assignment number and the name, address, and telephone number of the Scientific Review Administrator (SRA) of the Scientific Review Group (SRG) to which the application has been assigned. If this information is *not received within that time, contact*:

Division of Receipt and Referral
Center for Scientific Review, NIH
(301) 435-0715; Fax: (301) 480-1987

Sample Grant Application Assignment Number



G. Incomplete Applications

Do not submit an incomplete application. An application will be considered incomplete and will be returned if it is illegible, if it does not conform to the instructions, or if the material presented is insufficient to permit an adequate review. *If the proposed research involves human subject research or vertebrate animals, carefully read and follow the* Human Subjects Research *instructions in Section IV, Item 9.e of the Research Plan*.

H. Supplementary or Corrective Information

Should you discover an inadvertent error or omission after submitting your application, call 301-435-0715.

Supplementary or corrective material pertinent to the review of an application may be submitted after the receipt date, but only if it is specifically solicited by or agreed to through prior discussion with the Scientific Review Administrator (SRA) of the SRG. In no instance can the original Phase II application plus supplementary materials exceed the Phase II Research Plan page limitations.

VI. METHOD OF EVALUATION AND SELECTION CRITERIA

All Phase II grant applications will be evaluated and judged on a competitive basis. Initially, applications will be screened for responsiveness and to confirm

that the required instructions were completed. *Those applications found to be incomplete in any way or programmatically unrelated to the agency's mission will be returned without review* to the applicant small business concern. Applications passing this initial screening will be reviewed for technical and scientific merit by scientists, engineers and/or other persons who are experts in the scientific field in which you are proposing. Each application will be judged on its own merit, according to the review criteria described below. The participating agencies are under no obligation to fund any specific application or make any specific number of awards in a given research topic area. Also, they may elect to fund several or none of the proposed projects within a given topic area.

Evaluations of applications require, among other factors, *consideration of an application's commercial potential* as evidenced by the small business concern's record of commercializing SBIR/STTR or other research; the existence of second phase funding commitments from private sector or non-SBIR/STTR funding sources; the existence of third phase follow-on commitments for the subject of the research; and/or the presence of other indicators of the commercial potential of the idea.

A. Review Process

Grant applications are subjected to an external peer review process involving two sequential steps that are required by law. The first step is performed by the Scientific Review Groups (SRGs), composed primarily of non-Federal scientists, physicians, and engineers (from academia and industry) selected for their expertise and stature in particular scientific fields. The second step is performed by the National Advisory Council or Board of the potential awarding component (Institute, Center, or other unit) to which the grant application is assigned.

SCIENTIFIC REVIEW GROUPS

The first task of the SRGs is to evaluate each SBIR/STTR application for scientific and technical merit and potential for commercialization, and to make an SRG recommendation for each application on the basis of this evaluation. The SBIR/STTR review criteria are listed in Section C below.

While NIH uses a numerical range from 1.00 (most meritorious) to 5.00 (least meritorious), a streamlined procedure is used to determine those applications that the SRG considers to be in the "upper" or "lower half." Applications in the "upper half" are discussed by the SRG and these *generally* receive a score between 1.0 and 3.0, and applications in the "lower half" are not discussed and receive an "unscored" designation (i.e., those that would generally have received a score between 3.0 and 5.0). However, any review group member may identify an application that he or she believes should be discussed at the meeting and receive a numerical score. Under the currently employed streamlining procedures, a rating of 3.00 would be considered the median score for the cohort of applications that a scientific review group might review.

Individual reviewers mark scores to two significant figures, e.g., 1.5, and the individual scores are averaged and then multiplied by 100 to yield a single overall score for each scored application, e.g., 153. Abstaining members and those not present during the discussion do not assign a numerical rating and are not counted in calculating the average of the individual ratings.

The second task of the SRGs is to make budget recommendations concerning time and dollar amounts that are appropriate for the work proposed.

Regardless of the study section recommendation, all applicants receive a summary statement that includes a single rating/designation and the essentially unedited, verbatim critiques of two or more assigned reviewers.

NATIONAL ADVISORY COUNCIL OR BOARD

The second level of review is performed by the National Advisory Council or Board of the potential awarding component (Institute, Center, or other unit) to which the grant application is assigned. These groups, composed of scientists, physicians, and members of the public, are chosen for their expertise, interest, or activity in matters related to the awarding component's mission. In order for an application to be funded, it must be recommended by the Council or Board.

B. SBIR/STTR Review Criteria

"Formulae" do not exist for calculating an individual reviewer's score on an application. Remember, among several criteria, Phase II applications will be judged based on the results of Phase I, demonstration of feasibility, scientific and technical

merit, and commercial potential of the Phase II application. In considering the scientific and technical merit of each application, the following criteria will be used:

ALL SBIR/STTR APPLICATIONS

1. *Significance*
   a. Does the proposed project have commercial potential to lead to a marketable product or process? Does this study address an important problem?
   b. What may be the anticipated commercial and societal benefits that may be derived from the proposed research?
   c. If the aims of the application are achieved, how will scientific knowledge be advanced?
   d. Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries?
   e. Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs?
2. *Approach*
   a. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?
   b. Is the proposed plan a sound approach for establishing technical and commercial feasibility?
   c. Does the applicant acknowledge potential problem areas and consider alternative strategies?
   d. Are the milestones and evaluation procedures appropriate?
3. *Innovation*
   a. Does the project challenge existing paradigms or employ novel technologies, approaches or methodologies?
   b. Are the aims original and innovative?
4. *Investigators*
   a. Is the Principal Investigator capable of coordinating and managing the proposed SBIR/STTR?
   b. Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers, including consultants and subcontractors (if any)?
   c. Are the relationships of the key personnel to the small business and to other institutions appropriate for the work proposed?
5. *Environment*
   a. Is there sufficient access to resources (e.g., equipment, facilities)?
   b. Does the scientific and technological environment in which the work will be done contribute to the probability of success?
   c. Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

Human Subjects. In conducting peer review for scientific and technical merit, SRGs will also evaluate the involvement of human/animal subjects and proposed protections from research risk relating to their participation in the proposed Research Plan according to the following four review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits of the proposed research to the subjects and others, and (4) importance of the knowledge to be gained.

When human subjects are involved in the proposed clinical research, the SRG will also evaluate the proposed plans for inclusion of minorities and members of both sexes/genders, as part of the scientific assessment of Approach criterion.

Vertebrate Animals. The proposed involvement of vertebrate animals will be evaluated by SRGs as part of the scientific assessment of Approach and Environment criteria and according to the following five points: (1) detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) procedures for limiting pain and distress to that which is unavoidable; and (5) methods of euthanasia. See section in Research Plan on Vertebrate Animals.

These evaluations will be factored into the overall score for scientific and technical merit of the application.

In accordance with NIH policy, the following criteria will be applied to ALL applications:

Human Subjects

1. *Protection of Human Subjects from Research Risks* — for all studies involving human subjects. See instructions and "Guidance for Preparing the Human Subjects Research Section".
   a. If an exemption is claimed, is it appropriate for the work proposed? If no exemption is claimed, are the applicant's responses to the six required points appropriate?
   b. Are human subjects placed at risk by the proposed study? If so, are the risks reasonable in relation to the anticipated benefits to the subjects and others? Are the risks reasonable in relation to the importance of the knowledge that reasonably may be expected to be gained?
   c. Are the plans proposed for the protection of human subjects adequate?
2. *Inclusion of Women Plan – for clinical research only*.
   a. Does the applicant propose a plan for the inclusion of both genders that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent?
   b. Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?
3. *Inclusion of Minorities Plan – for clinical research only*
   a. Does the applicant propose a plan for the inclusion of minorities that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent?
   b. Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?
4. *Inclusion of Children Plan – for all studies involving human subjects*
   a. Does the applicant describe an acceptable plan in which the representation of children of all ages (under the age of 21) is scientifically appropriate and recruitment/retention is addressed realistically?
   b. If not, does the applicant provide an appropriate justification for their exclusion?
5. *Data and Safety Monitoring Plan – for clinical trials only*
   a. Does the applicant describe a Data and Safety Monitoring Plan that defines the general structure of the monitoring entity and mechanisms for reporting Adverse Events to the NIH and the IRB?

Animal Welfare

1. If vertebrate animals are involved, are adequate plans proposed for their care and use?
2. Are the applicant's responses to the five required points complete and appropriate?
3. Will the procedures be limited to those that are unavoidable in the conduct of scientifically sound research?

Budget

1. For all applications, is the percent effort listed for the PI appropriate for the work proposed?
2. On applications requesting up to $100,000 total costs, is the overall budget realistic and justified in terms of the aims and methods proposed?
3. On applications requesting over $100,000 in total costs, is each budget category realistic and justified in terms of the aims and methods?

Biohazards

1. Is the use of materials or procedures that are potentially hazardous to research personnel and/or the environment proposed?
2. Is the proposed protection adequate?

PHASE II APPLICATION REVIEW CRITERIA

In addition to the above criteria:

1. How well did the applicant demonstrate progress toward meeting the Phase I objectives, demonstrating feasibility, and providing a solid foundation for the proposed Phase II activity?
2. Did the applicant submit a concise Commercialization Plan (formerly Product Development Plan [PDP]) that adequately addresses the specific areas described in Item j of the Phase II Research Plan?
3. Does the project carry a high degree of commercial potential, as described in the Commercialization Plan?

Amended Applications

In addition to the above criteria, the following criteria will be applied to revised applications.

1. Are the responses to comments from the previous SRG review adequate?
2. Are the improvements in the revised application appropriate?

C. Release of Grant Application Information after Review

Following evaluation of your grant application by the SRG but prior to National Advisory Council or Board action, a summary statement will be sent automatically to the Principal Investigator. The identity of the reviewers will never be disclosed.

Applicants normally receive their summary statement within four to six weeks following the study section meeting in which it was reviewed. A "summary statement" documents the evaluation of an application by the SRG and conveys the SRG's recommendations to the awarding component and its Council or Board. The identity of the reviewers is never disclosed. No one other than the Principal Investigator (and appropriate NIH staff) may receive the summary statement and evaluation rating.

After the review meeting occurs, applicants are encouraged to address inquiries about review to their Program Director, rather than to review staff. After receipt/review of the summary statement, applicants are encouraged to contact their Program Director for guidance and advice.

Also following NIH peer review, applicant organizations will be notified of the need for review and certification for the proposed research by an OHRP- Registered Institutional Review Board (IRB). See http://ohrp.osophs.dhhs.gov to register an IRB. The certification of IRB approval from an official signing for the applicant organization must then be sent to and received by the Grants Management Office identified in the notice requesting IRB certification. This IRB certification must include: the PHS application number, title of the project, name of the Principal Investigator/Program Director, date of IRB approval, and appropriate signatures. You may also use optional Form 310, "Protection of Human Subjects" to provide IRB certification (see http://ohrp.osophs.dhhs.gov/humansubjects/assurance/OF310.rtf).

Any modifications in the Research Plan section of the application, required by the IRB, must be submitted with the follow-up certification. It is the responsibility of the Principal Investigator/Program Director and the applicant organization to submit the follow-up certification.

When a year will have elapsed between the initial IRB review date and the anticipated award date, awarding unit staff shall require re-review by the IRB and certification prior to award.

D. Funding Decisions

When making funding decisions, the awarding components take into consideration the following: (1) ratings resulting from the scientific and technical evaluation process; (2) areas of high program relevance; (3) program balance (that is, balance among areas of research); (4) available funds; and (5) the commercialization status where the small business concern has received more than 15 Phase II awards in the prior five (5) fiscal years, if applicable (see this application requirement under "Prior SBIR/STTR Phase II Awards" found in Section IV.D.9. Item Research Plan, Item k). The awarding component will notify the Principal Investigator and the applicant small business concern of the final disposition of the application.

Phase II applications will be selected for funding based on the project's scientific and technical merit, the awarding component's assessment of the Phase I progress report and determination that the Phase I goals were achieved, an update and verification of the Commercialization Plan (formerly Product Development Plan [PDP]) and any commitment(s) for funds and/or resources from an investor or partner organization, the project's potential for meeting the mission of the awarding component and potential for commercial success, and the availability of funds.

Fast-Track Phase II applications that are recommended for approval may be funded following submission of the Phase I progress report and other documents necessary for continuation.

E. Revision and Resubmission of Grant Applications

Grant applications that are not funded may be revised for resubmission on any of the published

receipt dates (e.g., Apr 1, Aug 1, Dec 1). However, applicant organizations may submit no more than two revised applications within a period of two years from the receipt date of the initial, original application. The limit of two revisions allows applicant small business concerns and Principal Investigators sufficient time to consider the comments of the reviewers and address them. If an applicant is not successful after three attempts at funding (the initial submission and two revisions), she/he is expected to make a significant change in the direction and approach for subsequent applications. It is not appropriate to submit an essentially identical or only slightly changed application as a new application.

Resubmitted applications without substantive changes will not be accepted. All revised applications must include an Introduction. See Section IV.D., Item 9, for specific instructions. The revised application MUST address the issues identified in the previous summary statement for the previous submission that was not funded. *Revised sections must be clearly marked by appropriate bracketing, indenting, or changing of typography, unless the changes are so extensive as to include most of the text*. This exception should be explained in the Introduction. *Do not shade changes*. Upon acceptance of a revised application by the CSR, the prior version will be withdrawn from further consideration by the awarding components. Acceptance of the revised application will generally mean that it will fall into a later review and award cycle. *Resubmission of an application that merely duplicates a previous application is not acceptable and the duplicate application will be returned without review*.

F. Submission of Similar Grant Applications by the Applicant Organization to Other Federal Agencies

WARNING: While it is permissible with application notification to submit identical applications or applications containing a significant amount of essentially equivalent work for consideration under numerous Federal program solicitations, it is unlawful to enter into funding agreements requiring essentially equivalent effort. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award.

If you elect to submit identical applications or applications containing a significant amount of essentially equivalent work under other Federal program solicitations, you must include the following information as part of your "Other Support" information when requested by NIH:

- Name and address of the agencies to which applications were submitted or from which awards were received.
- Date of application submission or date of award.
- Title, number, and date of solicitations under which application(s) was submitted or awards received.
- Specific applicable research topics for each application submitted or award received.
- Titles of research projects.
- Name and title of Principal Investigator or Project Manager for each application submitted or award received.

Submission of similar grant applications to the NIH by the same applicant small business concern is strongly discouraged.

Principal Investigators are cautioned not to prepare multiple grant applications with essentially the same research focus, that is, a product or technology that, with non-substantive modifications, can be applied to a variety of purposes. In evaluating groupings of applications with a common scientific focus or objective (for example, implantation sensors/sensor materials, medical applications of lasers, immunology/immunoassays), SRGs are in a position to easily identify multiple grant applications from the same small business concern for essentially the same project. In these cases, the HHS will give funding consideration to only one application.

VII. AWARD GUIDELINES, REPORTING REQUIREMENTS, AND OTHER CONSIDERATIONS

A. Awards

The primary award mechanism will be the grant instrument. The average dollar amount of Phase II awards (composed of direct costs, F&A/indirect costs, and profit/fee) is estimated to be approximately $750,000 for SBIR awards and STTR awards.

PHS awarding components may not always be able to honor the requested start date. No commitments or obligations should be made until confirmation of the actual start date by the awarding component.

B. Terms and Conditions of Award

Preaward Costs. A potential grantee may, *at its own risk* and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days prior to the effective date of a new or competing continuation award if such costs:

- Are necessary to conduct the project, and
- Would be allowable under the grant, if awarded, without NIH prior approval.

Upon acceptance of a grant award, the grantee must comply with the terms and conditions contained or referenced in the Notice of Grant Award document. These terms and conditions, constituting legal requirements imposed on an awardee by statute, regulations, administrative policy, or the award document itself, are either “standard” or “special” as follows:

Standard Terms and Conditions. Those that are required by policy to be incorporated by reference in Notices of Grant Award through citations of specific documents that contain requirements applicable to the grant.

Special Terms and Conditions. Those that are judged necessary to attain the objectives for which the grant is being awarded, facilitate post-award administration, conserve grant funds, or otherwise protect the interests of the Federal Government. They are stated in full on the Notice of Grant Award.

Grant awards must be administered in accordance with the *NIH Grants Policy Statement* (http://www.nih.gov/grants/policy/) and with the following regulations and policy:

9 CFR 1,2,3	Animal Welfare
37 CFR 401	Rights to Inventions Made by Non-profit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements
42 CFR 52	Grants for Research Projects
45 CFR 46	Protection of Human Subjects
45 CFR 74	Administration of Grants
45 CFR 80	Nondiscrimination Under Programs Receiving Federal Assistance Through DHHS Effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR 84	Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance
45 CFR 91	Nondiscrimination on the Basis of Age in Programs and Activities Receiving or Benefiting from Federal Financial Assistance
P.L. 99-158	Public Health Service Policy on Humane Care and Use of Laboratory Animals Section 495 “Animals in Research”
P.L. 100-690	Drug-Free Workplace Act of 1988 Title V, Subtitle D

C. Payment Schedule

Once an SBIR/STTR grant is awarded, the grantee will receive information and forms from the Payment Management System of the DHHS regarding requests for cash, manners of payment, and associated reporting requirements. Payment may be made on a cost-reimbursement or advance basis.

D. Reports and Related Information

NIH requires that SBIR/STTR grantees **submit the following reports within 90 days of the end of the grant support period** unless the grantee is under an extension.

- Financial Status Report (OMB 269, http://www.whitehouse.gov/omb/grants/index.html)
- Final Progress Report (no form)
- Final Invention Statement and Certification (HHS 568) Microsoft Word, Corel WordPerfect, and Adobe Acrobat format.
- Annual Invention Utilization Reports
- Final Cash Transaction Report (PSC 272, http://www.dpm.psc.gov/reports/forms/272.cfm)
- Phase II Data Collection Requirement for Government Tech-Net Database (http://technet.sba.gov) - due upon completion of Final Reports above.

Failure to submit timely final reports may affect future funding to the organization or awards with the same Principal Investigator.

Under the expanded authorities of NIH Grants Policy, the grantee organization may elect to extend the project period for up to 12 months without additional funds. At least 10 days prior to the original project end date, the grantee must NOTIFY the awarding agency GMO in writing (email or letter) of the extension. The notification must be signed by the authorizing business official and must include the new project end date. Extensions beyond the initial notification must be REQUESTED by the grantee organization and APPROVED by the awarding GMO.

Awardees are strongly encouraged to review the section later in this chapter regarding the PHS 2590 Non-Competing Progress Report. The PHS 2590 is the progress report application to determine continued funding (type 5) for multi-year projects.

FINANCIAL STATUS REPORT (FSR) (OMB 269)

As stated in the *NIH Grants Policy Statement*, October 1998, Part II, pages 83-84, a Financial Status Report (OMB 269) must be submitted within 90 days of the expiration date. Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee 0rganization.

The FSR 269 form is available electronically at http://www.whitehouse.gov/OMB/grants/index.html. FSRs may be transmitted electronically to the NIH's Office of Financial Management (OFM), which, for this purpose, is equivalent to submission to the GMO. Information about the electronic transmittal of FSRs may be obtained from OFM at (301) 496-5287. Otherwise, the Financial Status Report may be mailed to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room B1B05A, MSC 2050
Bethesda, MD 20892-2050

Prior to submitting FSRs to NIH, grantees must ensure that the information submitted is accurate, complete, and consistent with the grantee's accounting system. The signature of the authorized institutional official on the FSR certifies that the information in the FSR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal Government. *Filing a false claim may result in the imposition of civil or criminal penalties*.

FINAL PROGRESS REPORT

A Phase I Final Progress Report is required for all Phase II applications.

If you do not intend to submit a Phase II application within 90 days of the Phase I project period end date, then submit the *original and one copy of the Phase I Final Progress Report* to the Grants Management Office of the Awarding Component within 90 days of the termination of the Phase I grant.

There is no form page for the Final Progress Report. It may be typed on plain white paper and should include, at a minimum:

- Beginning and end dates for the period covered by the SBIR/STTR Phase I grant.
- Key personnel who worked on the project during that period (include titles, dates of service, and number of hours devoted to the project).

- Summary of the specific aims of the Phase I grant.
- Succinct account of published and unpublished results, indicating progress toward achievement of the originally stated aims.
- List of titles and complete references to publications, manuscripts accepted for publication, patents, invention reports and other printed materials, if any, that resulted from the Phase I.

The recommended length for the *narrative portion is 10 pages*.

FINAL INVENTION STATEMENT AND CERTIFICATION (HHS 568)

The grantee must *submit to the awarding component a Final Invention Statement and Certification (HHS-568)*, whether or not an invention(s) results from work under the grant. The final invention statement/certification must be signed by the Principal Investigator and an authorized institutional official and must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, from the original effective date of support through the date of expiration or termination, whether or not previously reported. If there were no inventions, the statement should indicate "None."

IMPORTANT: All inventions made in the course of, or under, any NIH research grant, including SBIR/STTR awards, must be promptly and fully disclosed to NIH within 2 months after the inventor provides written disclosure to the grantee's authorized official.

The *disclosure must be in writing*. Identify the applicable grant and the name of the inventor(s), and provide a complete technical description and other information as required by 37 CFR 401.14(c)(1) (see "Administrative Requirements Availability of Research Results: Publications and Intellectual Property Rights, Including Unique Research Resources" for the full text of the clause).

In addition to immediate invention disclosure, each application for competing or non-competing continuation support of an NIH grant-supported research project must include either a listing of all inventions conceived or reduced to practice during the preceding budget period or a certification that no inventions were made during the applicable period.

ANNUAL UTILIZATION REPORT

The grantee must also submit an annual utilization report when the grantee has elected title to an invention or when royalties or licensing fees are generated for inventions that are not patented. NIH has developed an optional online Extramural Invention Information Management System, known as "IEdison," to facilitate grantee compliance with the disclosure and reporting requirements of 37 CFR 401.14(h) (http://www.iedison.gov). *Information from these reports is not made publicly available*. For additional information on IEdison, see Section F, Inventions below.

A summary of grantee/contractor invention responsibilities, which provides information on time limits placed by law and identifies specific invention reporting actions that must be taken, is provided at http://www.iedison.gov/timeline.html.

PHASE II DATA COLLECTION REQUIREMENT FOR GOVERNMENT TECH-NET DATABASE

The SBA maintains a ''Technology Resources Access Network'' (Tech-Net) Database System to track and report on statistics regarding the SBIR and the STTR Programs.

Each Phase II applicant will be required to provide information to the SBA Tech-Net Database System (http://technet.sba.gov) for any of its prior Phase II awards.

In meeting this requirement, the small business concern may apportion sales or additional investment information relating to more than one Phase II award among those awards, if it notes the apportionment for each award. Each Phase II awardee is required to update the appropriate information in the Tech-Net database on that award upon completion of the last deliverable (e.g., Final Report, Financial Status Report, Invention Report) under the funding agreement. In addition, the awardee is requested to voluntarily update the appropriate information on that award in the Tech-Net database annually thereafter for a minimum period of 5 years.

Questions about this requirement may be submitted to SBA directly through the Tech-Net URL. To register on and use the Tech-Net database system, visit the Web site http://technet.sba.gov. Online help is available. SBA will minimize the data reporting

requirements of small business concerns, make updating available electronically, and provide standardized procedures.

Project commercialization and sales data can only be viewed by Congress, GAO, agencies participating in the SBIR and the STTR Programs, Office of Management and Budget (OMB), Office of Science and Technology Policy (OSTP), Office of Federal Procurement Policy (OFPP), and other authorized persons (for example, authorized contractors) who are subject to a use and nondisclosure agreement with the Federal Government covering the use of the database. Pursuant to 15 U.S.C. 638(k)(4), information provided to the Government Tech-Net Database is privileged and confidential and not subject to disclosure pursuant to 5 U.S.C. 552 (Government Organization and Employees); nor must it be considered to be publication for purposes of 35 U.S.C. 102 (a) or (b).

Examples of the data to be entered by applicants into Tech-Net include revenue from the sale of new products or services resulting from the research conducted under each Phase II award or additional investment from any source, other than Phase I or Phase II awards, to further the research and development conducted under each Phase II award.

NON-COMPETING GRANT PROGRESS REPORTS

http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-066.html

The PHS 2590 is the progress report application to determine continued funding (type 5) for multi-year projects. Awardees should be aware of the following information regarding submission of the PHS 2590 Non- Competing Grant Progress Report.

NIH continues to transition the notification of Non-Competing Grant Progress Reports from a hard copy mailing of preprinted electronic PHS 2590 face pages to an electronic format. As discussed in the May 2, 2002 Notice on this topic (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-047.html), the last hard copy mailing of pre-printed face pages was mailed in late June 2002 for those progress reports with November 2002 start dates.

Beginning with December 2002 start dates and beyond; e.g., those progress reports due on/after October 1, 2002, grantees will need to access a website to determine which progress reports are due. Progress reports should continue to be mailed directly to the NIH awarding Institute/Center. A list of Institute/Center mailing addresses for progress reports is found at: http://grants.nih.gov/grants/type5_mailing_addresses.htm.

Now available at: http://era.nih.gov/userreports/pr_due.cfm, the NIH Office of Extramural Research has launched a website of Non-competing Progress Report due date information. Grantee officials can query using their Institutional Profile Number (IPF) to return a list of "due" progress reports. If an official is not certain of the IPF, a companion query is also available at the site to help determine the appropriate IPF. Grantee officials should plan to review this list at least once a month.

Electronic submissions of the PHS 2590 (e-SNAPs) progress reports are due six weeks prior to the anticipated start date of the pending budget period. Non-electronic progress reports are due two months prior to the anticipated start date of the pending budget period.

Also, NIH strongly encourages all grantees to set up electronic (e-mail) notification for NIH grant awards. For instructions, please go to the following website: http://grants2.nih.gov/grants/guide/notice-files/not98-129.html.

E. Innovations, Inventions and Patents

LIMITED RIGHTS INFORMATION AND DATA

Proprietary Information

Information contained in unfunded grant applications will remain the property of the applicant. The Government may, however, retain copies of all applications submitted. Public release of information in any application submitted will be subject to existing statutory and regulatory requirements.

When the application contains information that constitutes trade secrets; or information that is commercial or financial; or information that is confidential or privileged, it will be treated in confidence. *Confidential, proprietary information must be clearly identified in the application by asterisks (*)*.

Also include the following legend in this section of the application or on PHS 398 Form Page 3 to identify the appropriate page numbers:

"These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this application. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained in pages _____ of this application."

Any other legend may be unacceptable to the Government and may constitute grounds for removing the application from further consideration, without assuming any liability for inadvertent disclosure. The Government will limit dissemination of such information to/within official channels.

Title to Equipment and Supplies

Title to equipment and supplies acquired by a for-profit organization as a grantee or subcontractor under a grant awarded by the agencies participating in this solicitation, shall vest, upon acquisition, in the grantee or subcontractor, respectively. Final disposition of equipment acquired with Federal funds by for-profit grantees is covered under 45 CFR 72.13(g).

Rights in Data Developed Under SBIR/STTR Funding Agreement

To preserve the SBIR data rights of the awardee, the legend (or statements) used in the SBIR Data Rights clause included in the SBIR award must be affixed to any submissions of technical data developed under that SBIR award. If no Data Rights clause is included in the SBIR award, the following legend, at a minimum, should be affixed to any data submissions under that award:

"These SBIR data are furnished with SBIR rights under Funding Agreement No. _____ (and subcontract No. _____ if appropriate), Awardee Name _____, Address, Expiration Period of SBIR Data Rights _____. The Government may not use, modify, reproduce, release, perform, display, or disclose technical data or computer software marked with this legend for (choose four (4) or five (5) years). After expiration of the (4- or 5-year period), the Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties, except that any such data that is also protected and referenced under a subsequent SBIR award shall remain protected through the protection period of that subsequent SBIR award. Reproductions of these data or software must include this legend."

Rights to data, including software developed under the terms of any funding agreement resulting from a grant application submitted in response to this solicitation, shall remain with the grantee, except that the Government shall have the limited right to use such data for internal Government purposes and shall not release such data outside the Government without permission of the grantee for a period of four years from completion of the project from which the data were generated.

Copyrights

The grantee may normally copyright and publish (consistent with appropriate national security considerations, if any) material developed with PHS support. The awarding component receives a royalty-free license for the Federal Government and requires that each publication contain an acknowledgment of agency support and disclaimer statement, as appropriate. An acknowledgment shall be to the effect that *"This publication was made possible by grant number _____ from (NIH/CDC/FDA awarding component)"* OR *"The project described was supported by grant number _____ from (NIH/CDC/FDA awarding component). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the (NIH/CDC/FDA awarding component)."*

Inventions

Refer to http://www.iedison.gov for more detailed information.

Any invention first conceived or reduced to practice with award funds must be reported to the NIH. *The inventor must report the discovery to the grantee organization promptly*. Within two months of the inventor's initial report to the grantee organization, the organization must report the invention to the NIH's Extramural Invention Reporting and Technology Resources Branch of the Office of

Policy for Extramural Research (see address in "Patents" section below). This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the small business concern, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

The reporting of inventions by the grantee organization to the NIH can be accomplished by submitting paper documentation, including fax, or electronically through the NIH Interagency Edison (IEdison) Invention Reporting System. Use of the IEdison system satisfies all mandated invention reporting requirements and access to the system is through a secure interactive Website (http://www.iedison.gov) designed to ensure that all information submitted is confidential.

In addition to fulfilling reporting requirements, IEdison notifies the user of future time-sensitive deadlines with enough lead-time to avoid the possibility of loss of patent rights due to administrative oversight. IEdison can accommodate the invention reporting needs of all organizations. For additional information about this invention reporting and tracking system, *visit the IEdison home page cited above or contact Edison via email at* edison@od.nih.gov.

Patents

Small business concerns normally retain the principal worldwide patent rights to any invention developed with Government support. Under existing regulations, 37 CFR 401, the Government receives a royalty-free license for Federal Government use, reserves the right to require the patent-holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States. The applicant small business concern is *strongly encouraged to obtain information about additional requirements imposed by 37 CFR 401 from local counsel or from*:

Extramural Inventions and Technology Resources Branch
Office of Policy for Extramural Research
National Institutes of Health
6705 Rockledge Drive, MSC 7980
Bethesda, MD 20892-7750
Phone: (301) 435-1986; Fax: (301) 480-0272
Email: george.stone@nih.gov or edison@od.nih.gov.

To the extent authorized by 35 U.S.C. 205, the Government will not make public any information disclosing a Government-supported invention for a four-year period from the date of disclosure (that may be extended by subsequent SBIR/STTR funding agreements) to allow the grantee a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

Research Tools/Unique Research Resources

It is the policy of the NIH to make available to the public the results and accomplishments of the activities it funds. Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research and delivery of medical care. Notices in the *NIH Guide for Grants and Contracts (Vol. 23, No. 26*, July 15, 1994, http://grants.nih.gov/grants/guide/notice-files/not94-216.html) and the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps_2001/part_iia_6.htm) fully explain the policy regarding the distribution of research resources developed with NIH funds.

The NIH encourages the commercialization of research products and allows grantee organizations to make materials available to others for commercial purposes with appropriate restrictions and licensing terms. Where the product of research developed with Federal funding is a patentable but unpatented research product, the terms of a license must be no more restrictive than they would have been if the product had been patented.

F. Joint Ventures and Limited Partnerships

Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern in accordance with the definition in Section III. Size determination of a joint venture entity requires that the combined total number of employees from all affiliates not exceed 500. Other criteria under the definition of a small business concern must also be met.

G. American-Made Equipment and Products

When purchasing equipment or a product under the SBIR/STTR award, the small business concern should purchase only American-made items whenever possible.

H. Profit or Fee

A reasonable profit/fee is available to small business concerns receiving awards under the SBIR/STTR program; *however, this profit/fee must be included in your budget request at the time of application*. The fee is not a "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. However, the amount of the fee approved by the agencies participating in this solicitation normally will not exceed 7% of total costs (direct and indirect) for each phase (I and II) of the project. *The profit/fee applies solely to the small business concern (grantee organization) receiving the SBIR/STTR award and not to any other participant in the project*. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

I. Additional Information

This Omnibus Solicitation is intended for informational purposes and reflects current planning. If there is *any inconsistency between the information contained herein and the terms of any resulting SBIR/STTR funding agreement, the terms of the funding agreement are controlling*.

Prior to award of an SBIR/STTR funding agreement, the Government may request the applicant small business concern to submit certain organizational, management, personnel, and financial information to ensure responsibility of the applicant organization.

This Omnibus Solicitation is not an offer by the Government and does not obligate the Government to make any specific number of awards. Awards under the SBIR/STTR program are contingent upon the scientific and technical merit and potential for commercialization of an application and the availability of funds for research and development. The Government is not responsible for any monies expended by the applicant organization before award of any funding agreement.

Phase II awards are contingent upon the results demonstrated in Phase I and the scientific and technical merit and commercial potential of the Phase II application and the availability of funds for research and development. The incurrence of costs by the small business concern prior to the award of a grant imposes no obligation on the Government to either make the award or increase the amount of the award.

If an award is made pursuant to a grant application submitted in response to this Omnibus Solicitation, the grantee may be required to certify that it has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government. See Section III for the definition of "essentially equivalent work."

If an award is made under this Omnibus Solicitation for a project, some of whose elements are being or will be supported by another Federal agency, the awarding component and the applicant organization will negotiate a budget that reflects the elimination of any overlapping support.

J. Cost Sharing

Cost sharing is permitted for SBIR/STTR applicants, however it is not required, and it will not be a review criterion. If you are cost sharing the project, be sure that the costs reflected on the budget page(s) are only those Federal funds that you are requesting from the SBIR Program. You may state in the budget justification or elsewhere in the application your plans to cost share.

K. Audit Requirements of For-Profit Organizations

The Department of Health and Human Services (HHS) has specified requirements for non-Federal audits of for-profit (commercial) organizations in HHS' Title 45, Code of Federal Regulations (CFR), Part 74.26, "Non-Federal Audits." Per the regulations, a for-profit (commercial) organization is subject to audit requirements for a non-Federal audit if, during its fiscal year, it expended $300,000 or

more under HHS awards and at least one award is an HHS grant.

Title 45 CFR Part 74.26 essentially incorporates the thresholds and deadlines of Office of Management and Budget (OMB) Circular No. A-133, "Audits of States, Local Governments and Non-Profit Organizations," but provides for-profit organizations with two options regarding the type of audit that will satisfy the audit requirements either: (1) a financial related audit (as defined in the Government Auditing Standards, GPO Stock #020-000-00-265-4, http://www.gao.gov/govaud/ybk01.htm) of all the HHS awards in accordance with Government Auditing Standards, or (2) an audit that meets the requirements contained in OMB Circular No. A-133, http://www.whitehouse.gov/omb/circulars/a133/a133.html.

Audits shall be completed and submitted to the office shown below within a period that is either (1) the earlier of 30 days after receipt of the auditor's report(s), or (2) nine months after the end of the audit period (i.e., the organization's fiscal year).

National External Audit Resources
HHS Office of Audit Services
Lucas Place
323 West 8th Street, Room 514
Kansas City, MO 64105

The HHS will be identifying organizations not meeting audit requirements. Failure to comply may jeopardize eligibility for receiving future HHS awards.

L. Time and Effort Reporting for Commercial Organizations

POLICY

Commercial (for-profit) organizations must document salaries and wages charged to contracts and grants by maintaining a labor distribution system for all employees regardless of function. The labor distribution system must account for total hours and charge direct and indirect labor to the appropriate cost objectives to accurately identify labor costs:

- Charged to direct projects.
- Charged to indirect activities.
- Included in the base to which indirect costs are allocated.

Internal Controls

Timekeeping procedures and controls on labor charges are of utmost concern. Unlike other costs, labor is not supported by external documentation or physical evidence, which provides independent checks and balances. It is critical that managers indoctrinate individual employees on their independent responsibility for accurately recording their time. Internal controls over labor charging should meet the following criteria:

- Responsibility for timekeeping and payroll accounting should be separated.
- Procedures must be clear and reasonable so there is no confusion regarding the rationale for the controls or misunderstanding as to what is and is not permissible.
- Maintenance of controls must be verified continually, and violations must be acted upon promptly and effectively to serve as a deterrent to prospective violations.
- Individual employees must be constantly made aware of controls that act as an effective deterrent against violations. This awareness can be accomplished by emphasizing the importance of accurate time and effort reporting in orientation sessions, periodic meetings, and the posting of messages as reminders.
- Changes on timesheets to the number of hours recorded or the cost center identified should be made by the employee and must be initialed by the employee.
- Company policy must state that the nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant, or other factors.
- Company policy should emphasize that complete and accurate time and effort reporting is an important part of an employee's job. Careless or improper reporting may lead to disciplinary actions under company policies as well as applicable Federal statutes.

Time and Effort Documentation Requirements and Responsibilities

Detailed instructions for time documentation should be established in written company procedures. A manual system would require handwritten pen and ink entries on a paper timesheet reflecting all the

days in the pay period. An automated timekeeping system typically would use remote data entry for recording labor charging data and sending it directly to a central computer for processing. Supporting documentation for an automated system would normally consist of computer printouts showing data that appear on source documents, i.e., timesheets in a manual system.

Employee Responsibilities

Whether a manual or automated time and effort reporting system is in place, the employee is personally responsible for:

- After the fact recording of hours (or fractions thereof) on a daily basis.
- Recording all hours worked and all hours absent. All hours should be recorded whether or not they are paid.
- Recording of hours on the timesheet in ink (manual system only).
- Recording the correct distribution of hours by project or indirect category. The nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant, or other factors.
- To ensure accuracy, a listing of project numbers/indirect categories and their descriptions should be provided in writing to each employee.
- Any changes/corrections to timesheets should be made by the employee and must show what was initially recorded, i.e., no erasures or "white out" of entries.
- The employee also must initial any change(s).
- At the end of each pay period, the employee must sign the timesheet or electronically certify the labor distribution in an automated system.

Supervisor Responsibilities

- An authorized company official (e.g., supervisor) must cosign timesheets or electronically certify individual time and effort reporting at the end of each pay period.
- The supervisor is prohibited from completing an employee's timesheet or entering hours in an automated system unless the employee is absent for an extended period of time on some form of authorized leave.

VIII. SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Health science research literature is available at academic and health science libraries throughout the United States. Information retrieval services are available at these libraries and Regional Medical Libraries through a network supported by the National Library of Medicine. To find a Regional Medical Library in your area, visit http://nnlm.gov/ or contact the Office of Communication and Public Liaison at publicinfo@nlm.nih.gov, (301) 496-6308.

Other sources that provide technology search and/or document services include the organizations listed below. They should be contacted directly for service and cost information.

National Technical Information Service
1-800-553-6847
http://www.ntis.gov

National Technology Transfer Center
Wheeling Jesuit College
1-800-678-6882
http://www.nttc.edu/

Regional Technology Transfer Centers
1-800-472-6785
http://www.ctc.org/NewFiles/RTTCs.html

IX. MODEL AGREEMENT FOR ALLOCATION OF RIGHTS

The STTR legislation (Public Law 107-50, as amended) and the STTR Policy Directive of the Small Business Administration (SBA), require that agencies participating in the STTR program provide guidance for allocating between small business concerns and research institutions intellectual property rights and rights, if any, to carry out follow-on research, development or commercialization. Included in this solicitation, is the guidance as approved by the SBA and the Office of the General Counsel, HHS. The document, entitled "Model Agreement, Small Business Technology Transfer (STTR) Program, Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-on Research, Development, or Commercialization,"

may be photocopied freely. The parties to the Agreement are advised that this "model" may be revised through negotiation between the small business concern and the single, "partnering" research institution.

The *Agreement is a requirement to receive support under the STTR program. Therefore, by signing the Face Page of the grant application, the Official Signing for Applicant Organization (small business concern) certifies that the Agreement with the research institution will be effective at the time of award*. A copy of the Agreement must be furnished upon request of the NIH awarding component.

X. ASSURANCES, CERTIFICATIONS AND OTHER POLICY ISSUES

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application.

The assurances listed and explained below may or may not be applicable to your project, program, or type of applicant organization. There are a number of additional public policy requirements with which applicants and grantees must comply. Refer to your institution's research grant administrative office or the *NIH Grants Policy Statement* for additional information. A copy of the *NIH Grants Policy Statement* may be obtained from the NIH Website (http://grants.nih.gov/grants/policy/policy.htm). In signing the application Face Page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with the following policies, assurances and/or certifications:

A. Human Subjects

(See Section III for definition of human subjects.) The DHHS regulations, for the protection of human subjects, provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that applicant organizations proposing to involve human subjects in nonexempt research, file a written Assurance of Compliance with the Office for Human Research Protections (OHRP), establishing appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR 46, Protection of Human Subjects, are available from the OHRP, National Institutes of Health, Rockville, MD 20892, (301) 496-7041.

Investigators, who conduct research involving pregnant women, human fetuses and neonates, prisoners, or children, must follow the provisions of the regulations in Subparts B, C, and D, respectively, of 45 CFR 46, which describe the additional protections required for these subjects.

No non-exempt research involving human subjects can be conducted under a DHHS award unless that organization is operating in accord with an approved Assurance of Compliance and provides certification that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the DHHS regulations. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the DHHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations.

The Center of Biologics Evaluation and Research (CBER), FDA, regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies and gene therapies. If your work involves these areas or preclinical research that will support later work in these areas, please see the Office of Recombinant DNA Activities Website at http://www4.od.nih.gov/oba/.

Under DHHS regulations to protect human subjects from research risks, certain research areas are exempt. (See Exemption Categories in the Research Plan section.)

Nonetheless, studies that are exempt from the human subjects regulations must still address the inclusion of women and minorities in clinical research in the study design. Therefore, applications will be evaluated for compliance with this policy. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually

identifiable are also to be included within the term "research involving human subjects."

B. Research on Transplantation of Human Fetal Tissue

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, DHHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure DHHS access to those records, if maintained by an entity other than the applicant organization.

C. Women and Minority Inclusion In Clinical Research Policy

Research involving human subjects must comply with the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." The following excerpts provide the key policy statements. Investigators should obtain full copies of the current amended Guidelines that were published in the NIH Guide at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html.

The policy of NIH is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects in clinical research, unless a clear and compelling rationale and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a description of the proposed outreach programs for recruiting women and minorities as participants.

Funding: Awards will not be made if the research project does not comply with this policy. In addition, awardees must report annually on enrollment of women and men, and on the race and ethnicity of research participants in the "*5/01 Inclusion Enrollment Report Format Page* (RTF | PDF)."

D. Inclusion of Children Policy

Research involving children must comply with the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects," issued March 6, 1998. The following excerpts provide the key policy statements. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from the NIH grants Website under the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/notice-files/not98-024.html).

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. This policy applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accord with Section 401 (b) of 45 CFR 46 Subpart A - Federal Policy for the Protection of Human Subjects. The inclusion of children as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the State or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

E. Research Using Human Embryonic Stem Cells

(See http://www.nih.gov/news/stemcell/index.htm.) In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research using human embryonic stem cells is proposed, the applicant organization will be in compliance with the "*Notice of Extended Receipt Date and Supplemental Information Guidance for Applications Requesting Funding that Proposes Research with Human Embryonic Stem Cells*" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-006.html).

F. Vertebrate Animals

The PHS Policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."

NIH policy requires, prior to award, the submission of Institutional Animal Care and Use Committee (IACUC) approval when animal studies are involved.

In accordance with the 2002 change in PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/fed_reg_v67n152.pdf) the verification of IACUC approval may be submitted subsequent to peer review and at any time prior to award unless specifically required earlier by NIH or other PHS agencies. In no case may PHS agencies make an award (competing or non-competing) without verification of IACUC approval.

If the IACUC verification is not submitted with the application, the follow-up verification must include the PHS application number, title of project, name of PI, institution/applicant organization, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures. Any modification of the Research Plan section of the application or in the proposed use of animals, required by the IACUC, must be clearly described and submitted with the follow-up verification.

The PHS *Policy on Humane Care and Use of Laboratory Animals* requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This Policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval.

G. Debarment and Suspension

Executive Order 12549, "Debarment and Suspension," mandated development of a Government-wide debarment and suspension system for nonprocurement transactions with Federal agencies. Executive Order 12689 and

Section 2455 of the Federal Acquisition Streamlining Act of 1994 further required Federal agencies to establish regulations for reciprocal Government-wide effect across procurement and nonprocurement debarment and suspension actions. This reciprocity rule is effective for any debarment, suspension or other Government-wide exclusion initiated on or after August 25, 1995. DHHS regulations implementing Executive Orders 12549 and 12689, and Section 2455 of the Federal Acquisition Regulation, are Provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the applicant organization must make the following certification (Appendix A of the DHHS regulations):

"1. The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals (including research personnel):

   a. Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

   b. Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

   c. Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

   d. Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

2. Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal."

Grantees are required to obtain a similar certification from most subawardees, called "lower tier participants." (See 45 CFR 76, Appendices A and B.)

H. Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) requires that all grantees receiving grants from any Federal agency certify to that agency that they will maintain a drug-free workplace. DHHS regulations implementing the Act are provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the applicant organization must make the certification set forth below (Appendix C of the DHHS regulations). The certification is a material representation of fact upon which reliance will be placed by the PHS awarding component. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or Government-wide suspension or debarment.

The applicant organization certifies, "that it will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about:

   (i) The dangers of drug abuse in the workplace;

   (ii) The grantee's policy of maintaining a drug-free workplace;

   (iii) Any available drug counseling, rehabilitation, and employee assistance programs, and

   (iv) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

(i) abide by the terms of the statement; and (ii) notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than 5 calendar days after such conviction;

(e) Notifying the agency in writing within 10 calendar days after receiving notice under subparagraph (d)(ii) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(ii), with respect to any employee who is so convicted:

(i) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(ii) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f)."

For purposes of paragraph (e), regarding agency notification of criminal drug convictions, the DHHS has designated the following central point for receipt of such notices:

Division of Grants Management and Oversight
Office of Management and Acquisition
Department of Health and Human Services
Room 517-D
200 Independence Avenue, S.W.
Washington, DC 20201

I. Lobbying

Title 31, United States Code, Section 1352, entitled "Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions," generally prohibits recipients of Federal grants and cooperative agreements from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific grant or cooperative agreement. Section 1352 also requires that each person who requests or receives a Federal grant or cooperative agreement must disclose lobbying undertaken with non-Federal (nonappropriated) funds. These requirements apply to grants and cooperative agreements exceeding $100,000 in total costs. DHHS regulations implementing Section 1352 are provided in 45 CFR Part 93, "New Restrictions on Lobbying."

The complete Certification Regarding Lobbying is provided below.

"The undersigned (authorized official signing for the applicant organization) certifies, to the best of his or her knowledge and belief that:

"(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

"(2) If any funds other than Federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

"(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants,

loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

"This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure."

Standard Form LLL, "Disclosure of Lobbying Activities," its instructions, and continuation sheet are available from GrantsInfo, National Institutes of Health, email: GrantsInfo@nih.gov, (301) 435-0714.

J. Non-Delinquency on Federal Debt

The Federal Debt Collection Procedure Act, 28 U.S.C. 3201 (e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the authorized organizational official of the applicant organization (or individual in the case of an individual National Research Service Award) certifies, by means of his/her signature on the application, that the organization is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal Government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed.

K. Research Misconduct

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science" and (2) 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers" (effective on the date set forth in the final rule).

The signature of the official signing for the applicant organization on the Face Page of the application serves as certification that:

1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;
2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;
3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

"Misconduct in Science" and "Research Misconduct" are defined by the Public Health Service as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation or judgments of data."

For further information, please contact:

Office of Research Integrity
Division of Education and Integrity
Rockwall II, Suite 700
5515 Security Lane
Rockville, MD 20852,
Phone: (301) 443-5300
Fax: (301) 594-0042 or (301) 445-5351.

L. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination)

Before a grant award can be made, a domestic applicant organization must certify that it has filed with the DHHS Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88352, as amended), which prohibits discrimination on the basis of race,

color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L. 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance Form HHS 690 is available from http://forms.psc.gov/forms/HHS/hhs.html.

Assurance of Compliance Form HHS 690 is now used in lieu of individual assurances: Form HHS 441, Civil Rights; Form HHS 641, Handicapped Individuals; Form HHS 639-A, Sex Discrimination; and Form HHS 680, Age Discrimination.

M. Financial Conflict of Interest

NIH requires grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." These requirements promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator.

The signature of the authorized organizational official on the Face Page of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F, including that:

1. There is in effect, at the organization, a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
2. Prior to the expenditure of any NIH funds awarded under a new award, the organization will inform NIH of the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations;
3. The Institution will continue to make similar reports on subsequently identified conflicts; and it will make information available to NIH, upon request, as to how identified conflicting interests have been handled.

N. PHS Metric Program

Consistent with Government-wide implementing regulations, 15 CFR Part 19, Subpart B and/or any other Government-wide requirements, PHS policy is to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

O. Smoke-Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

P. Prohibition on Awards to 501(c)4 Organizations That Lobby

Organizations described in section 501(c)4 of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive grant/cooperative agreement awards. This is not to be confused with 45 CFR Part 93, Section 1352, "New Restrictions on Lobbying." See subsection I, Lobbying.

Q. Government Use of Information Under Privacy Act

The Privacy Act of 1974 (5 U.S.C. 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following

notification to each individual whom it asks to supply information.

The PHS maintains applications and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder PHS' ability to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services and outside the agency to the public, as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including the Congress acting within its legislative authority, the National Archives, the General Accounting Office, the Bureau of Census, law enforcement agencies, and pursuant to a court order. Information may also be disclosed outside the Department, if necessary, for the following purposes:

1. To a Congressional office at the request of the record subject;
2. To the Department of Justice as required for litigation;
3. To the cognizant audit agency for auditing;
4. To qualified experts not within the definition of Department employees as prescribed in Department Regulations (45 CFR 5b.2) for opinions as part of the application review/award process;
5. For an authorized research purpose under specified conditions;
6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;
7. To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and
8. To the applicant organization in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

R. Information Available to the Principal Investigator

Under the provisions of the Privacy Act, Principal Investigators may request copies of records pertaining to their grant applications from the PHS component responsible for funding decisions. Principal Investigators are given the opportunity under established procedures to request that the records be amended if they believe they are inaccurate, untimely, incomplete, or irrelevant. If the PHS concurs, the records will be amended.

S. Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, the Principal Investigator, and the amount of the award. The description, on Form Page 2 of a funded research grant application is sent to the National Technical Information Service (NTIS), U.S. Department of Commerce, where the information is used for the dissemination of scientific information and for scientific classification and program analysis purposes. These descriptions are available to the public from the NTIS.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants, upon request, irrespective of the intended use of the information. Trade secrets and commercial, financial, or otherwise intrinsically valuable information that is obtained from a person or organization and that is privileged or confidential information may be withheld from disclosure. Information, which, if disclosed, would be a clearly unwarranted invasion of personal privacy, may also be withheld from disclosure. Although the grantee institution and the Principal Investigator will be consulted about any such release, the PHS will make the final determination. Generally available for release, upon request, except as noted above, are: all funded grant applications including their derivative funded noncompeting supplemental grant applications; pending and funded noncompeting continuation applications; progress reports of

grantees; and final reports of any review or evaluation of grantee performance conducted or caused to be conducted by the DHHS. Generally, not available for release to the public are: competing grant applications (initial, competing continuation, and supplemental) for which awards have not been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups.

T. Recombinant DNA and Human Gene Transfer Research

The National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) apply to NIH-funded and non-NIH-funded gene transfer projects that are conducted at or sponsored by an institution that receives NIH support for recombinant DNA research. As defined by the NIH Guidelines, recombinant DNA molecules are either: (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of those described in (1). The NIH Guidelines set forth principles and standards for safe and ethical conduct of recombinant DNA research and apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in the appendix of the document (Appendix M). The NIH Guidelines should be carefully reviewed to ensure compliance with all other requirements for the conduct of projects involving recombinant DNA research and human gene transfer. Failure to comply with the NIH Guidelines may result in suspension, limitation, or termination of NIH funds for recombinant DNA research at the organization or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization. A copy of *the NIH Guidelines* is posted at the following URL: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and may be obtained from the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838.

U. Other Support Policy

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.

Information on Other Support should *not* be submitted with the application. If other support information is included in the application, the application will be returned to the applicant organization without peer review.

This information is required for all applications that are to receive grant awards; however, NIH will request complete and up to date "Other Support" information from applicants at an appropriate time after peer review. The Institute's scientific program and grants management staff will review this information prior to award.

Information on other support assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and only funds necessary to the conduct of the approved project are included in the award.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

Commitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application. While information on other support is only requested for key personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent.

Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source. Potential scientific overlap is to be addressed by the Scientific Review Group *only* by its

identification in an Administrative Note in the Summary Statement.

Resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the Principal Investigator, and awarding agency staff.

SUBMISSION OF OTHER SUPPORT INFORMATION

Information on other support should ONLY be submitted when requested by the NIH Institute/Center (I/C).

The following discussion on Other Support is for informational purposes only, so you understand what will be required when NIH staff request your Other Support documentation. There is no form page for other support. Follow the sample format on the "Other Support Format Page" (RTF | PDF). The sample is intended to provide guidance regarding the type and extent of information requested.

Information on active and pending other support is required for key personnel, excluding consultants. For individuals with no active or pending support, indicate "None." Neither the application under consideration nor the current PHS award for this project should be listed as other support.

If the support is provided under a consortium/subcontract arrangement or is part of a multi-project award, indicate the project number, Principal Investigator, and source for the overall project and provide all other information for the subproject only.

INSTRUCTIONS FOR SELECTED ITEMS REQUIRED ON "OTHER SUPPORT"

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent Effort: For an active project, provide the level of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the level of effort as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort. (See beginning of this section, Other Support, to view definitions of the three types of overlap.)